

12-01-03

DAC #17

STRADLING YOCCA CARLSON & RAUTH

A PROFESSIONAL CORPORATION

ATTORNEYS AT LAW

660 NEWPORT CENTER DRIVE, SUITE 1600

NEWPORT BEACH, CA 92660-6422

TELEPHONE (949) 725-4000

FACSIMILE (949) 725-4100

SAN FRANCISCO OFFICE
44 MONTGOMERY STREET, SUITE 4200
SAN FRANCISCO, CALIFORNIA 94104
TELEPHONE (415) 283-2240
FACSIMILE (415) 283-2255

SANTA BARBARA OFFICE
302 OLIVE STREET
SANTA BARBARA, CALIFORNIA 93101
TELEPHONE (805) 584-0065
FACSIMILE (805) 584-1044

LOUIS C. CULLMAN

DIRECT DIAL: (949) 725-4154
LCULLMAN@SYCR.COM



RECEIVED

DEC 04 2003

OFFICE OF PETITIONS

CERTIFICATE OF EXPRESS MAIL

I hereby certify that on November 26, this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage in an envelope addressed to: Mail Stop: Patent Term Extension, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

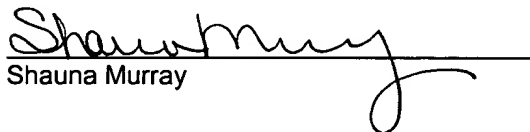
37 C.F.R. § 1.8(a)

☐ with sufficient postage
as first class mail

37 C.F.R. § 1.10

☒ as "Express Mail Post Office to
Addressee" Mailing Label No.

EV 308811820 US


Shauna Murray

APPLICATION FOR PATENT TERM EXTENSION UNDER 35 U.S.C. § 156

Mail Stop: Patent Term Extension
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

RE: Application for Patent Term Extension Pursuant to 35 U.S.C. § 156 (37 C.F.R.
§ 1.740) United States Patent Number 6,344,053

Dear Commissioner:

Enclosed is an application for patent term extension pursuant to 37 C.F.R. § 1.740. The owner (assignee) of record, Medtronic Vascular (formerly Medtronic AVE) is submitting this application. All rights in United States Patent Number (USPN) 6,344,053 are held by and vested in Medtronic Vascular a Delaware Corporation and a wholly owned subsidiary of Medtronic, Inc., a Delaware company. Medtronic Vascular's corporate headquarters are located at 3576 Unocal Place, Santa Rosa, CA 95403. A brief chain of title summary follows.

10/05/2005 TDEY11 00000002 012525 6344053

01 FC:1457

1120.00 DA

Michael D. Boneau is the sole inventor of USPN 6,344,053 which is a continuation of United States Patent Application Serial Number (USPASN) 08/471,738, filed Jun. 6, 1995, now USPN 5,891,140, which is a divisional of USPASN 08/172,420, filed on Dec. 22, 1993, now abandoned, which is a division of USPASN 07/398,180, filed Aug. 24, 1989, now U.S. Pat. No. 5,292,331. Boneau assigned his entire right, title and interest in USPASN 07/398,180 together with all divisional

BEST AVAILABLE COPY

applications, continuations and continuations-in-part to Accuterix, Inc. its successors, legal representatives and assigns on August 24, 1989. The assignment was recorded in the United States Patent and Trademark Office (USPTO) on August 24, 1989. A complete microfilm copy is available in the USPTO records on reel 5116, frame 0570.

Subsequently, Accutrix, Inc. assigned their entire right, title and interest to USPASN 07/398,180 together with all divisional applications, continuations and continuations-in-part to Endovascular Support Systems, Inc. on August 9, 1991. A complete microfilm copy is available in the USPTO records on reel 5816, frame 0215.

Thereafter, Endovascular Support Systems, Inc. assigned their entire right, title and interest to USPASN 07/398,180 together with all divisional applications, continuations and continuations-in-part to Applied Vascular Engineering, Inc. September 8, 1993. This assignment was recorded in the USPTO on September 8, 1993. A complete microfilm copy is available in the USPTO records on reel 6687, frame 0449.

On January 30th, 1996 Applied Vascular Engineering, Inc. changed its name to Arterial Vascular Engineering, Inc. Applied Vascular Engineering then assigned its entire right, title and interest to USPASN 07/398,180 together with all divisional applications, continuations and continuations-in-part to Arterial Vascular Engineering. This assignment was executed January 30th, 1996 and was recorded March 20, 1996. A complete microfilm copy is available in the USPTO records on reel 8522, frame 0049.

Medtronic, Inc. acquired the assets of Arterial Vascular Engineering (AVE) through acquisition on January 29th, 1999 and formed a new Delaware Corporation named Medtronic AVE. Arterial Vascular Engineering assigned its entire right, title and interest to USPASN 07/398,180 together with all divisional applications, continuations and continuations-in-part to Medtronic AVE. This assignment was executed January 28th, 1999 and was recorded January 31, 1999. A complete microfilm copy is available in the USPTO records on reel 011258, frame 0053.

Subsequently, Medtronic AVE changed its name to Medtronic Vascular, the present applicant, wherein all right, title and interest to USPASN 07/398,180 together with all divisional applications, continuations and continuations-in-part now reside. Therefore, the application for patent term extension, Medtronic Vascular, is the owner of all rights title and interests in USPN 5,879,382, the subject patent of the present patent term extension application.

Documents supporting the above title chain for USPN 5,879,382 can be found in Appendix A of this application for patent term extension.

- 1) Complete Identification of the Approved Product by appropriate chemical and generic name, physical structure or characteristics:

The approved product is an over-the-wire coronary stent system for use in patients with symptomatic ischemic heart disease due to discrete single de novo and restenotic lesions. The FDA product code is MAF for Stents, Coronary. The Medtronic Vascular stent marketed as the "S8 Over-the-Wire System" or alternatively under the trademarked name "Driver Stent Delivery System." The System includes a cobalt-based modular stent mounted on a balloon catheter as depicted in Figure 1 below¹. Figure 2 shows the distal portion of the Medtronic Driver Stent Delivery System in detail. Figure 3 depicts a S8 modular stent member.

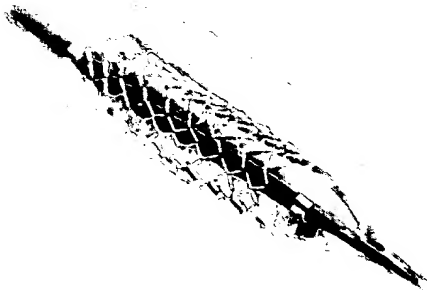


Figure 1

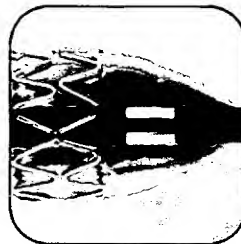


Figure 2



Figure 3

- 2) A complete identification of the Federal statute including the applicable provision of law under which the regulatory review occurred:

The Federal Statute under which regulatory review took place for the Medtronic Vascular's S8 Over-the-Wire System is 37 C.F.R. §814.

- 3) The date on which the product received permission for commercial marketing or use under the provision of law which the applicable regulatory review period occurred.

The Medtronic Vascular S8 Over-the-Wire System was approved for marketing October 1, 2003.

- 4) Statement that the present application is being submitted within the sixty day period permitted for submission and an identification of the date of the last day on which the application could be submitted.

The present application for patent term extension is being submitted with the sixty day period permitted for submission pursuant to 37 C.F.R. §1.720(f). The last day for submission of the

¹ See http://www.medtronic.com/medtronic_vascular/cs_drivermx.html

present application is November 30, 2003. However, because November 30, 2003 is a Sunday, this application may be mailed December 1, 2003.

- 5) The complete identification of the patent for which an extension is being sought by the name of the inventor, the patent number, the date of issue and the expiration date.

The present application for extension is for United States Patent Number 6,344,053 issued February 5, 2002 and expiring October 8, 2009. The inventor is Michael D. Boneau.

- 6) A copy of the entire patent for which extension is being sought, including the entire specification, claims and drawing.

A copy of U.S. patent number 6,344,053 is attached as Appendix B.

- 7) A copy of any disclaimer, certificate of correction, receipt of maintenance fee payment, or reexamination certificate issued in the patent.

There are no disclaimers or reexamination certificates issued on U.S. patent number 6,344,053. A copy of the maintenance fee payment record is provided as Appendix C. A copy of the Certificate of Correction is attached as Appendix D

- 8) Statement that the patent claims the approved product, or a method of using or manufacturing the approved product, and a showing which lists each applicable patent claim and demonstrates the manner in which at least one such patent claims reads on the approved product.

United States patent number 6,344,053 claims the S8 Over-the-Wire Coronary Stent System approved October 1, 2003. The applicant also asserts that claims 1-4, 6-11, 13-19, and 21-30 of the '053 patent read on the Medtronic Vascular S8 Over-the-Wire Coronary Stent.

In particular, claim 16 reads on the approved device as follows:

Claim Chart Comparing Claim 16 of U.S. Patent 6,344,053 element-by-element with the
S8 Over-the-Wire Coronary Stent

Claim 16 of U.S. Patent 6,344,053	Corresponding Features of the S8 Over-the-Wire Coronary Stent System
16. A balloon-expandable stent comprising:	The S8 is a coronary stent is a balloon expandable stent. See Figure 1 of this application compared with FIG. 7 of the '053 patent.
a plurality of adjacent and non-overlapping, generally circular members, each circular member including a plurality of substantially straight, non-overlapping segments having ends;	The S8 coronary stent is composed of a plurality of generally circular members as depicted in Figures 1 and 2 of the present application. Individual stent members as used in reference to the '053 patent are depicted in Figure 3 of the present application and Figure 1 of the '053 patent. See Figure 3 of this application below compared to Figure 1 of the 6,344,053 patent. It can be seen that the S8 stent member in Figure 3 of this application comprises a plurality of substantially straight non-overlapping segments having ends. The corresponding structures are seen in Figure 1 of the '053 patent at number 16 (the substantially straight non-overlapping segments) and at number 12 and 14 (the ends).
the ends of respective pairs of the plurality of segments connected to each other, the segments not connected at any point intermediate their ends;	Individual stent members as used in reference to the '053 patent are depicted in Figure 3 of the present application and Figure 1 of the '053 patent. See Figure 3 of this application below compared to Figure 1 of the 6,344,053 patent. It can be seen in Figure 3 of this application that the S8 stent has pairs of the plurality of segments that are not connected at any point intermediate to their ends.
each circular member capable of retaining a compressed configuration while mounted onto an outer surface of a balloon catheter until application of a radial force to form an expanded configuration; and	See Figure 3 of this application below compared to Figure 1 of the 6,344,053 patent. It can be seen that the S8 stent member segments in Figure 3 of this application are connected end to end at a plurality of axial turns. The corresponding structures are seen in Figure 1 of the '053 patent at numbers 12 and 14.
wherein each segment is aligned generally parallel to a longitudinal axis of the balloon catheter, when in a compressed configuration mounted on an outer surface of a balloon catheter.	The S8 stent is designed to be compressed onto a catheter's outer surface as depicted in Figure 4 of this application. Note also, that the segments are generally aligned parallel to the balloon's longitudinal axis when in the compressed configuration.

The pictures and Figures that follow correlate to the claim elements discussed in the Claim Chart on the preceding page and clearly demonstrate that Claim 16 of U.S. patent 6,344,053 (the '053 patent) reads on the S8 Over-the-Wire Coronary Stent System.

Figure 1 of U.S. patent 6,344,053

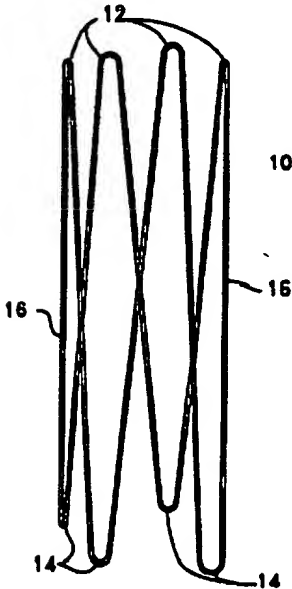
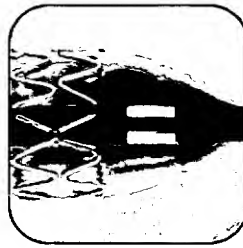


Figure 2 of this application: A plurality of S8 stent members attached end-to-end.²



In Figure 1 of US Patent 6,344,053 the upper axial turns (12) are connected to the lower axial turns (14) by substantially straight segments 16. The corresponding structures are clearly evident in Figures 2 and 3 of this application and juxtaposed to Figure 1 of the '053 patent.

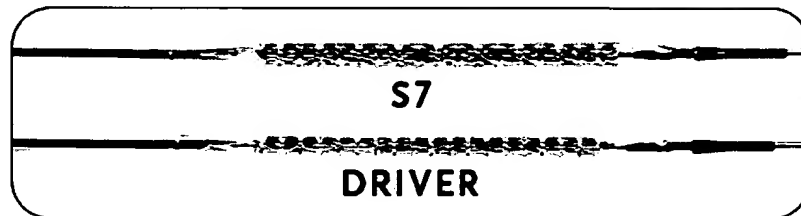
Figure 3 (below) of this application depicts a plurality of S8 stent segments connected end to end at a plurality of axial turns.³



² See http://www.medtronic.com/medtronic_vascular/cs_drivermx.html

³ See http://www.medtronic.com/medtronic_vascular/cs_drivermx.html

Figure 4 (below) of this application depicts the “Driver” (AKA S8Coronary stent) compressed onto catheter for delivery to an affected vessel.³



Note how the individual segments are aligned parallel to the balloon axis when the S8 stent is in the compressed state. Therefore, based on the analysis above the Applicant respectfully asserts that Claim 16 of United States Patent number 6,344,053 reads on the approved device, the Medtronic Vascular S8 Over-the-Wire Coronary Stent.

Figure 7 of the '053 patent (below) shows the stent as claimed in the expanded configuration on a catheter balloon. Compare this with the Driver Stent (S8) expanded on a balloon catheter immediately below.

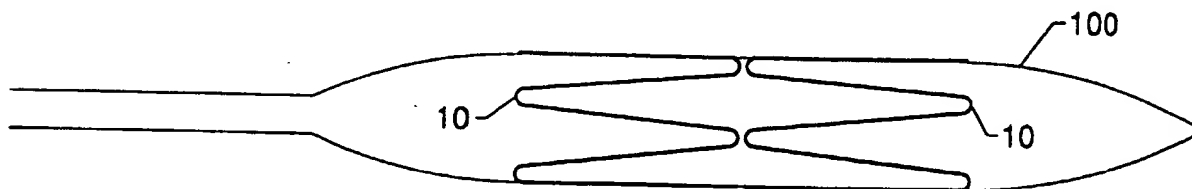


Figure 7

Figure 1 of this application showing the S8 stent balloon mounted and forcibly expanded.



New Page:

9) The relevant dates and information pursuant to 35 U.S.C. §156(g) to enable the Secretary of Health and Human Services to determine the applicable review period:

A) The effective date of the investigational device exemption (IDE) and the IDE number:

- 1) Conditional approval of the Applicant's IDE was dated December 20, 2001 and signed by Dr. Bram Zuckerman, Acting Director, Division of Cardiovascular and Respiratory Diseases.
- 2) The Applicant's IDE number is G010301, G010301/A1, A2 and A3.

B) The date on which the application for product approval under Section 515 of the Federal Food Drug and Cosmetic Act was initially submitted and the number of the application.

- 1) A Pre-market Approval application (PMA) for the S8 Over-the-Wire Coronary Stent System was submitted April 9, 2003.
- 2) The PMA number is P030009.

C) The date on which the application was approved.

The S8 Over-the-Wire Coronary Stent System PMA was approved on October 1, 2003.

New Page:

- 10) Brief Description of the significant activities undertaken by the marketing applicant (Medtronic Vascular) during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities.

No.	FDA Reviewer	Date	Description
G010301	Carolyn Vaughan	21-Nov-01	Original Driver Over-the-Wire Delivery System IDE Submission
G010301 / A001	Carolyn Vaughan	29-Nov-01	Submission provided on CD-ROM
G010301 / A002	Carolyn Vaughan	12-Dec-01	Histopathology/photomicrographs sent for GLP - 237
G010301 / A003	Carolyn Vaughan	14-Dec-01	List of Investigational Sites
NA	Bram Zuckerman	20-Dec-01	Conditional Approval Letter received from FDA
NA	NA	21-Dec-01	Fax sent to accounts informing them of conditional approval from FDA
G010301 / S001	Bram Zuckerman	01-Feb-02	Response to FDA Conditional Approval Letter Dated December 20, 2001
G010301 / S002	IDE Doc. Mail Ctr	05-Feb-02	Request for addition of patient guide to supply to patients
NA	NA	08-Feb-02	First patient implant for IDE Trial
G010301 / S003	IDE Doc. Mail Ctr	09-Apr-02	Report of status with ongoing animal studies
G010301 / S004	IDE Doc. Mail Ctr	11-Apr-02	Request extension to deadlines put forth in conditional approval letter
G010301 / S005	IDE Doc. Mail Ctr	22-Apr-02	Request approval for addition of 10 clinical trial sites
NA	NA	19-Apr-02	Teleconference regarding statistical questions received from the Driver conditional approval letter.
G010301 / S006	Donna-Bea Tillman	17-May-02	Response to FDA Conditional Approval Letter submitted
G010301 / S006	Donna-Bea Tillman	10-Jun-02	Approval of Driver IDE received from FDA
G010301 / S007	IDE Doc. Mail Ctr	17-Jun-02	6-Month Clinical Site Update submitted

10) Brief Description of the significant activities undertaken by the marketing applicant (Medtronic Vascular) during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities. (Continued).

No.	FDA Reviewer	Date	Description
NA	Ashley Boam	19-Aug-02	FDA determines based on new material of stent, the Driver PMA submission must be an original PMA, not a PMA supplement
G010301 / S008	IDE Doc. Mail Ctr	26-Aug-02	Report of status with ongoing animal studies
NA	NA	25-Sep-02	Last patient implant for IDE Trial
G010301 / S009	Bram Zuckerman	17-Oct-02	Report of status with ongoing animal studies
G010301 / S010	IDE Doc. Mail Ctr	23-Dec-02	Submission to FDA: Response to letter dated 11/14/2002 Final Animal Study Report (FS81)
G010301 / S011	IDE Doc. Mail Ctr	15-Jan-03	Submission response to request for additional information
G010301 / S012	IDE Doc. Mail Ctr	16-Jan-03	Annual Report Submitted
NA	Sue Bowley/ Ashley Boam	28-Feb-03	Teleconference regarding inclusion of 270-day clinical data as PMA Amendment.
P030009	PMA Doc Mail Ctr	9-Apr-03	Original FDA PMA Submission of Driver Coronary Stent Systems
P030009	Bram Zuckerman	23-May-03	FDA agreed to file PMA
P030009 / A001	PMA Doc Mail Ctr	3-Jul-03	Response submitted to FDA regarding questions from email dtd 27-May-03
P030009 / A002	PMA Doc Mail Ctr	11-Aug-03	270 day clinical data, changes to the packaging of the Over-The-Wire and Rapid Exchange delivery systems and proposed manufacturing changes to the Multi-Exchange delivery system
P030009 / A003	PMA Doc Mail Ctr	13-Aug-03	Response submitted to FDA regarding questions from email dated 12-Jul-03
P030009 / A004	PMA Doc Mail Ctr	15-Aug-03	Authorization letter for the FDA to discuss Driver PMA / STED with MHLW in Japan
P030009	Sue Bowley	19-Aug-03	Request from FDA for an additional hard copy of PMA Amendment which included 270d clinical data.
P030009 / A005	PMA Doc Mail Ctr	21-Aug-03	To notify FDA of findings from an internal audit performed by the Atlanta Cardiovascular Research Institute (ACRI) related to animal study FS70

10) Brief Description of the significant activities undertaken by the marketing applicant (Medtronic Vascular) during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities. (Continued)

No.	FDA Reviewer	Date	Description
NA	Sue Bowley/ Steve Hilbert	21-Aug-03	Samples of the OTW delivery system provided to reviewers at the request of FDA.
NA	NA	21-Aug-03	STED Desk Copies submitted to FDA
P030009	Ashley Boam	22-Aug-03	FDA confirmed with MHLW permission for cooperative review of STED
P030009 / A006	PMA Doc Mail Ctr	5-Sep-03	Request the withdrawal of Nutek Corp, located in Hayward, CA, from our list of sterilization facilities for the Driver coronary stent systems
NA	Sue Bowley/ Ashley Boam	14-Sep-03	Conclusion reached regarding format of compliance chart
P030009	Ashley Boam	22-Sep-03	Agreement with FDA to include claim for direct stenting in IFU
P030009 / A007	PMA Doc Mail Ctr	22-Sep-03	Response submitted to FDA regarding questions from email dated 17-Sep-03
P030009	Sue Bowley	25-Sep-03	90-day Status e-mail received
P030009 / A008	PMA Doc Mail Ctr	29-Sep-03	Response to FDA questions on final labeling, biomaterials compendium and conditions of approval letter
P030003	Bram Zuckerman	1-Oct-03	Driver PMA Approval received from FDA
P030009 / A009	PMA Doc Mail Ctr	8-Oct-03	Final Labeling

New Page:

- 11) Statement that in the opinion of the applicant that the patent is eligible for extension and a statement as to the length of extension claimed, including how the extension was calculated.

The applicant respectfully asserts that United States Patent Number 6,344,053 is eligible for extension. The applicant has demonstrated that at least one claim of U.S. Patent 6,344,053 reads on the approved device (S8 Over-the-Wire Coronary Stent) and that this application for extension is being timely filed.

The applicant respectfully asserts that U.S. Patent 6,344,053 is eligible for a 389 day extension as calculated pursuant to 37 CFR §1.777.

Calculations Under 37 CFR §1.777

1. Calculations under 37 CFR §1.777 (c)(1)

Determine the number of days in the period beginning on the date a clinical investigation on humans involving the device began and ending the date the PMA was initially submitted.

- i) Clinical investigations on humans are deemed to have begun on the date that the FDA determines that an IDE required under section 520(g) of the FDCA (21 U.S.C. 360j (g) is substantially complete. In this case the records indicated that on December 20, 2001 the Medtronic Vascular IDE number G010301, G010301/A1, A2 and A3 received a Conditional Approval. Thus, this date will be used for the initial calculations .
- ii) The PMA was initially filed April 9, 2003.
- iii) The experimental period is thus calculated as the time between December 20, 2001 and April 9, 2003, or **476 days**.

2. Calculations under 37 CFR §1.777 (c)(2)

Determine the number of days in the period beginning on the date the PMA was initially filed and ending on the date the PMA was approved.

The PMA was initially submitted April 9, 2003 and was approved October 1, 2003. Thus the approval period was **175 days**.

The Sum of 37 CFR §1.777 c(1) and 37 CFR §1.777 (c)(2) equals 651 days.

3. Calculations under 37 CFR §1.777 (d)(1)

- i) Subtract the number of days in the periods (c)(1) and (c)2 of this section which were on and before the date the patent issued.

48 days in period (c)(1) for U.S. Patent 6,344,053.

476 – 48 = 428 days

- ii) Subtract the number of days in the periods (c)(1) and (c)2 of this section during which the applicant did not act with due diligence.

Zero for U.S. Patent 6,344,053.

- iii) Subtract one-half the number of days remaining in the period defined by (c)(1) of this section after that period is reduced in accordance with paragraphs (d)(1)(i) and (ii).

214 days for U.S. Patent 6,344,053.

Therefore, the maximum extension available for U.S. patent number 6,344,053 For U.S. is **428 (from step 3 (i)) + 175 (from step 2) – 214 (from step 3 (iii)) = 389 days.**

4. Calculations Under 37 CFR §1.777 (d)(2)

Determine the number of days shortened by a terminal disclaimer.

Zero for U.S. Patent 6,344,053

5. Calculations Under 37 CFR §1.777 (d)(3)

Section (d)3 requires that 14 years be added to the date the PMA was approved, this equals the longest possible extension available (14 years from the approval date) in this case the 37 CFR §1.777 (d)(3) date is October 1, 2017).

6. Calculations Under 37 CFR §1.777 (d)(4)

The new expiration date is November 1, 2010 which is before October 1, 2017. Thus United States Patent 6,344,053 is eligible for the entire 389 day extension as calculated above.

7. Calculations Under 37 CFR §1.777 (d)(5)

United States Patent number 6,344,053 was filed after September 24, 1984.

- 12) Statement that the applicant acknowledges a duty to disclose to the Commissioner of Patents and trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought.

The applicant acknowledges his duty to disclose to the Commissioner of Patents and trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought. The applicant has no disclosures to that are material to the determination of entitlement to the extension sought.

- 13) The prescribed fee for receiving and acting upon the application for extension.

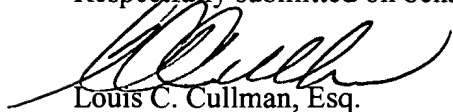
The Commissioner is hereby authorized to charge payment of the patent term extension application fee pursuant to 37 C.F.R. §1.20 (j)(1) in the amount of \$1,120.00 to Deposit Account number 01-2525.

- 14) The name address and telephone number of the person to whom inquires and correspondences relating to the application for patent term extension are to be directed.

Michael J. Jaro, Esq.
Chief Patent Counsel
Medtronic Vascular
3576 Unocal Place
Santa Rosa, CA 95403

(707) 566-1746

Respectfully submitted on behalf of the applicant,



Louis C. Cullman, Esq.
USPTO Reg. No. 39,645
Stradling Yocca Carlson & Rauth



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20531

RECEIVED
HARRISON & EAKIN
A Partnership of HARRISON & EAKIN, INC.

DEC 14 1989

DBM	_____	Lib	_____
JEE	_____	ST	_____
JKC	_____	DOCKET	_____
MW	_____	FILE	_____

TO: JAMES E. EAKIN
HARRISON & EAKIN
1700 SOUTH EL CAMINO REAL, STE 405
SAN MATEO, CA 94402-3083

UNITED STATES PATENT AND TRADEMARK OFFICE
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE U.S. PATENT AND TRADEMARK OFFICE ON THE REEL AND FRAME NUMBER REFERENCED BELOW. A DIGEST OF THE DOCUMENT HAS ALSO BEEN MADE AND APPEARS IN THE OFFICE'S RECORDS AS SHOWN:

ASSIGNOR: 001 BONEAU, MICHAEL D.

DOC DATE: 08/24/89

RECORDATION DATE: 08/24/89 NUMBER OF PAGES 002 REEL/FRAME 5116/0570

DIGEST: ASSIGNMENT OF ASSIGNORS INTEREST

ASSIGNEE: 501 ACCUTERIX, INC., 342 W. SUNNYOAKS, CAMPBELL, CALIFORNIA 95008, A CORP. OF CA

SERIAL NUMBER 7-398180 FILING DATE 08/24/89
PATENT NUMBER ISSUE DATE 00/00/00

TITLE OF INVENTION: ENDOVASCULAR SUPPORT DEVICE AND METHOD

INVENTOR: 001 BONEAU, MICHAEL D.

SEND STD LTR
TO BONEAU, COPY
TO STERILIZER BUT
WE KEEP ORIG.
JEE

ASSIGNMENT

1
2 WHEREAS, I, MICHAEL D. BONEAU, a citizen of the United States of America,
3 residing at 342 W. Sunnyoaks, Campbell, California 95008, have invented a certain
4 new and useful ENDOVASCULAR SUPPORT DEVICE AND METHOD for which I am
5 about to make an application for Letters Patent of even date herewith; and

6 WHEREAS, ACCUTERIX, INC., a corporation existing under the laws of the
7 State of California and doing business at 342 W. Sunnyoaks, Campbell, California
8 95008, is desirous of obtaining the entire right, title and interest in, to and under the
9 said invention and application.

10 NOW, THEREFORE, for good and valuable consideration, the receipt of which
11 is hereby acknowledged, I, MICHAEL D. BONEAU, have sold, assigned, transferred
12 and set over, and by these presents do hereby sell, assign, transfer and set over
13 unto the said ACCUTERIX, INC, its successors, legal representatives and assigns,
14 my entire right, title and interest in, to and under the said invention and the said
15 application for Letters Patent, a copy of which as filed in the United States Patent
16 Office is contained in Docket No. H-1136-P in the offices of HARRISON & EAKIN, a
17 Partnership of Professional Corporations, 1700 South El Camino Real, Suite 405, San
18 Mateo, California 94402-3083 and all divisions, continuations and continuations-in-
19 part thereof, and all Letters Patent of the United States which may be granted
20 thereon and all applications for Letters Patent which may be filed for said invention
21 in any country or countries foreign to the United States, and all Letters Patent which
22 may be granted for said invention in any country or countries foreign to the United
23 States, and to all extensions, renewals, and reissues thereof, and the right to claim
24 priority under the International Convention for the Protection of Industrial Property;
25 and I hereby authorize and request the Commissioner of Patents and Trademarks
26 of the United States, and any Official of any country or countries foreign to the
27 United States whose duty it is to issue patents on applications as aforesaid, to issue
28 all Letters Patent for said invention to the said ACCUTERIX, INC., its successors,
29 legal representatives and assigns, in accordance with this instrument.

30 AND I hereby covenant that I have the full right to convey my entire interest
31 herein assigned, and that I have not executed, and will not execute, any agreement
32 in conflict herewith.

1 AND I hereby further covenant and agree that I will communicate to the said
 2 ACCUTERIX, INC., its successors, legal representatives and assigns, any facts known
 3 by me respecting said invention, and testify in any legal proceeding, sign all lawful
 4 papers, execute all divisional, continuing or reissue applications, make all rightful
 5 oaths, and generally do everything possible to aid the said ACCUTERIX, INC., its
 6 successors, legal representatives and assigns to obtain and enforce proper patent
 7 protection for said invention in all countries.

8 IN TESTIMONY WHEREOF, I have hereunto set my hand this Twenty-Fourth
 9 day of August, 1989, at Santa Clara, California.

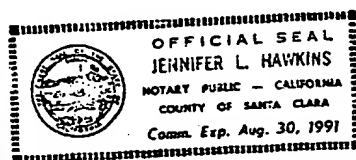
10
 11 
 12 Michael D. Boneau

13 STATE OF CALIFORNIA

14 COUNTY OF Santa Clara

15 } ss.


16 On this Twenty-Fourth day of August, 1989, before me personally appeared
 17 Michael D. Boneau, personally known to me or proved to me on the basis of
 18 satisfactory evidence to be the person whose name is subscribed to the within
 19 instrument, and acknowledged that he executed it. Witness my hand and official
 20 seal.



22 
 23 Notary Public

24 RECORDED
 25 PATENT & TRADEMARK OFFICE

26 AUG 24 89

27 
 28 COMMISSIONER OF PATENTS
 29 AND TRADEMARK OFFICE
 30
 31
 32



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

DATE: 09/18/91

TO:

JAMES E. EAKIN

HARRISON & EAKIN

1700 SOUTH EL CAMINO REAL, STE 405

SAN MATEO, CA 94402-3083

UNITED STATES PATENT AND TRADEMARK OFFICE
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE U.S. PATENT AND TRADEMARK OFFICE ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT ASSIGNMENT PROCESSING SYSTEM. IF YOU SHOULD FIND ANY ERRORS, ON THIS NOTICE, PLEASE SEND A REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT BRANCH, NORTH TOWER BUILDING, SUITE 10C35, WASHINGTON, D.C. 20231

ASSIGNOR:

ACCUTERIX, INC., A CORPORATION OF CA

DOC DATE: 08/09/91

RECORDATION DATE: 08/23/91 NUMBER OF PAGES 003 REEL/FRAME 5816/0215

DIGEST :ASSIGNMENT OF ASSIGNORS INTEREST

ASSIGNEE:

ENDOVASCULAR SUPPORT SYSTEMS, INC.

A CORPORATION OF CA

342 W. SUNNYOAKS

CAMPBELL, CALIFORNIA 95008

SERIAL NUMBER	7-398180	FILING DATE	08/24/89
PATENT PATENT		ISSUE DATE	00/00/00

RECEIVED
Law Office of
JAMES E. EAKIN, P.C.

OCT 15 1991

EE _____ JC _____
DOCKET _____

H-1136-P

1 it is to issue patents on applications as aforesaid, to issue all Letters Patent for said
2 invention the said ENDOVASCULAR SUPPORT SYSTEMS, INC., its successors, legal
3 representatives and assigns, in accordance with this instrument;

4 AND, ACCUTERIX, INC., hereby covenant that it have the full right to convey
5 my entire interest herein assigned, and that I have not executed, and will not execute,
6 any agreement in conflict therewith;

7 AND, ACCUTERIX, INC., hereby further covenant and agree that it will
8 communicate to the said ENDOVASCULAR SUPPORT SYSTEMS, INC., its successors,
9 legal representatives and assigns, any facts known to it respecting said invention and
10 said application, and testify in any legal proceedings, execute all lawful papers, make
11 all rightful oaths and generally do everything possible to aid the said ENDOVASCULAR
12 SUPPORT SYSTEMS, INC., its successors, legal representatives and assigns to obtain
13 and enforce proper patent protection for said invention in all countries.

14 IN TESTIMONY WHEREOF, ACCUTERIX, INC., through an authorized officer,
15 has caused this Assignment to executed this 9 day of AUG. 1991.

16
17 RECEIVED
PATENT AND TRADEMARK
OFFICE

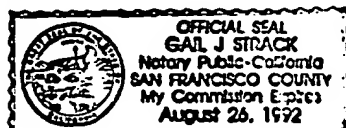
18 Ben Hidalgo
Ben Hidalgo,
Secretary & Treasurer
ACCUTERIX, INC.

19
20 State of California
21 County of San Mateo

22 On 9th day of August, 1991 before me, Gail J. Strack personally
23 appeared Ben Hidalgo, personally known to me (or proved to me on the basis of
24 satisfactory evidence) to be the person whose name is subscribed to the within
instrument and acknowledged to me that he executed the same in his authorized
25 capacity, and that by his signature on the instrument the person, or the entity upon
behalf of which the person acted, executed the instrument.

26 WITNESS my hand and official seal.

27 Signature Gail J. Strack Seal



REC-16 1991 17

ASSIGNMENT

WHEREAS, ACCUTERIX, INC., a corporation existing under the law of the State of California and doing business at 342 W. Sunnyoaks, Campbell, California 95008, is the owner by assignment of U.S. Patent Application Serial Number 07/398,180, filed August 24, 1989, entitled ENDOVASCULAR SUPPORT DEVICE AND METHOD together with all right, title and interest in, to and under the invention described therein including all foreign rights thereto; and

WHEREAS, ENDOVASCULAR SUPPORT SYSTEMS, INC., a corporation existing under the laws of the State of California and doing business at 342 W. Sunnyoaks, Campbell, California 95008, is desirous of obtaining the entire right, title and interest in, to and under the said application, including all foreign rights;

NOW, THEREFORE, in consideration of a good and valuable consideration, the receipt of which is hereby acknowledged, ACCUTERIX, INC., have sold, assigned, transferred and set over, and by these presents do hereby sell, assign, transfer and set over unto the said ENDOVASCULAR SUPPORT SYSTEMS, INC., its successors, legal representatives and assigns my entire right, title and interest in, to and under the said invention and the said application of Letters Patent Serial No. 07/398,180 filed August 24, 1989, and all divisions, continuations and continuations-in-part thereof, and all Letters Patent of the United States which may be granted thereon and all application for Letters Patent which may be granted for said invention in any country or countries foreign to the United States of America, and to all extensions, renewal, reissues, and reexamination certificates thereof, and the right to claim priority under the International Convention of the Protection of Industrial Property, and all rights under the Patent Cooperation Treaty; and ACCUTERIX, INC., hereby authorize and request the Commissioner of Patents and Trademarks of the United States of America, and any official of any country or countries foreign to the United States whose duty

916424916

ASSIGNMENT

WHEREAS, ENDOVASCULAR SUPPORT SYSTEMS, INC., formerly named ENDOTHELIAL SUPPORT SYSTEMS, INC., a corporation existing under the laws of the State of California and doing business at 342 W. Sunnyoaks, Campbell, California 95008, is the owner by assignment of U.S. Patent Application Serial Number 07/398,180, filed August 24, 1989, entitled ENDOVASCULAR SUPPORT DEVICE AND METHOD, together with all right, title and interest in, to and under the invention described therein including all foreign rights thereto; and

WHEREAS, APPLIED VASCULAR ENGINEERING, INC., a corporation existing under the laws of the State of Delaware and doing business at 5345 Skylane Boulevard, Santa Rosa, CA 95403 is desirous of obtaining the entire right, title and interest in, to and under the said invention and application, including all foreign rights;

NOW, THEREFORE, for good and valuable consideration, the receipt of which is hereby acknowledged, ENDOVASCULAR SUPPORT SYSTEMS, INC., have sold, assigned, transferred and set over, and by these presents do hereby sell, assign, transfer and set over unto the said APPLIED VASCULAR ENGINEERING, INC., its successors, legal representatives and assigns, its entire right, title and interest in, to and under the said invention and the said application for Letters Patent serial number 07/398,180, filed August 24, 1989, and all divisions, continuations and continuations-in-part thereof, and all Letters Patent of the United States which may be granted thereon and all applications for Letters Patent which may be filed for said invention in any country or countries foreign to the United States, and all Letters Patent which may be granted for said invention in any country or countries foreign to the United States, and to all extensions, renewals, and reissues thereof, and the right to claim priority

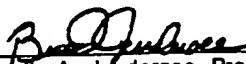
H-1136-P

under the International Convention for the Protection of Industrial Property; and ENDOVASCULAR SUPPORT SYSTEMS, INC., hereby authorizes and requests the Commissioner of Patents and Trademarks of the United States, and any Official of any country or countries foreign to the United States whose duty it is to issue patents on applications as aforesaid, to issue all Letters Patent for said invention to the said APPLIED VASCULAR ENGINEERING, INC., its successors, legal representatives and assigns, in accordance with this instrument.

AND ENDOVASCULAR SUPPORT SYSTEMS, INC., hereby covenants that it has the full right to convey its entire interest herein assigned, and that it has not executed, and will not execute, any agreement in conflict herewith.

AND ENDOVASCULAR SUPPORT SYSTEMS, INC., hereby further covenants and agrees that it will communicate to the said APPLIED VASCULAR ENGINEERING, INC., its successors, legal representatives and assigns, any facts known by it respecting said invention, and testify in any legal proceeding, sign all lawful papers, execute all divisional, continuing or reissue applications, make all rightful oaths, and generally do everything possible to aid the said APPLIED VASCULAR ENGINEERING, INC., its successors, legal representatives and assigns to obtain and enforce proper patent protection for said invention in all countries.

IN TESTIMONY WHEREOF, ENDOVASCULAR SUPPORT SYSTEMS, INC., through an authorized officer, has caused this Assignment to be executed this Eighth day of September, 1993, at Santa Rosa, California.



Brady A. Jendersee, President
ENDO VASCULAR SUPPORT SYSTEMS, INC.



7-081

D

RECORDATION FORM COVER SHEET PATENTS ONLY

To the Hon. Commissioner of Patents & Trademarks: Please record the attached original documents.

1. Name of conveying party(ies):
ENDOVASCULAR SUPPORT SYSTEMS, INC.

2. Name and address of receiving party(ies):

Name: APPLIED VASCULAR ENGINEERING, INC.

Street Address: 5345 SKYLANE BLVD.

City: SANTA ROSA State: CA Zip: 95401

Additional name(s) of conveying party(ies)

Attached? Yes X No

3. Nature of Conveyance:

XX Assignment Merger
 Security Agreement Change of Name
 Other

Execution Date:

Additional name(s) & addresses attached?
Yes XX No

4. Application Number(s) or patent number(s):

If this document is being filed together with a new application, the execution date of the application is:

A. Patent Application No. (s)
07/398,180

B. Patent No. (s)

Additional numbers attached? Yes XX No

5. Name and address of party to whom correspondence concerning document should be mailed

Name: LAW OFFICES OF JAMES E. EAKIN

Street Address: 1301 SHOREWAY RD., STE. 324

City: BELMONT State: CA Zip: 94002-4106

6. Total number of applications and patents involved 1

7. Total fee(37CFR3.41)\$ 40.00

XX Enclosed

 Authorized to be charged to deposit account.

8. Deposit Account Number 05-0150
(Attach duplicate copy of this page if paying by Deposit Account)

9. Statement and signature.

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document. 91695613

JAMES E. EAKIN
Name of Person Signing

[Signature]
Signature

8 SEP 93
Date

Total number of pages comprising cover sheet: 1

Mail documents to be recorded with required cover sheet information to:

Hon. Commissioner of Patents and Trademarks
Box: Assignments
Washington, D.C. 20231



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

JULY 01, 1997

PTAS

ARTERIAL VASCULAR ENGINEERING
RICHARD L. KLEIN
3576 UNOCAL PLACE
SANTA ROSA, CA 95403



100425106A

UNITED STATES PATENT AND TRADEMARK OFFICE
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION
CONTAINED ON THIS RECORDATION
PATENT AND TRADEMARK AS:
HAVE QUESTIONS CONCERNING
NAME APPEARS ON THIS NOTICE
CORRECTION TO: U.S. PATENT
BOX ASSIGNMENTS, NORTH T

*Name
Change
from
Applied
to Arterial*

IS NOTICE. THE INFORMATION
THE DATA PRESENT IN THE
YOU SHOULD FIND ANY ERRORS OR
CONTACT THE EMPLOYEE WHOSE
PLEASE SEND REQUEST FOR
CE, ASSIGNMENT DIVISION,
0C35, WASHINGTON, D.C. 20231.

RECORDATION DATE: 05/19/97

REEL/FRAME: 8522/0049
NUMBER OF PAGES: 6

BRIEF: CHANGE OF NAME (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:

APPLIED VASCULAR ENGINEERING, INC. DOC DATE: 01/29/1996

ASSIGNEE:

ARTERIAL VASCULAR ENGINEERING, INC.
3576 UNOCAL PLACE
SANTA ROSA, CALIFORNIA 95403

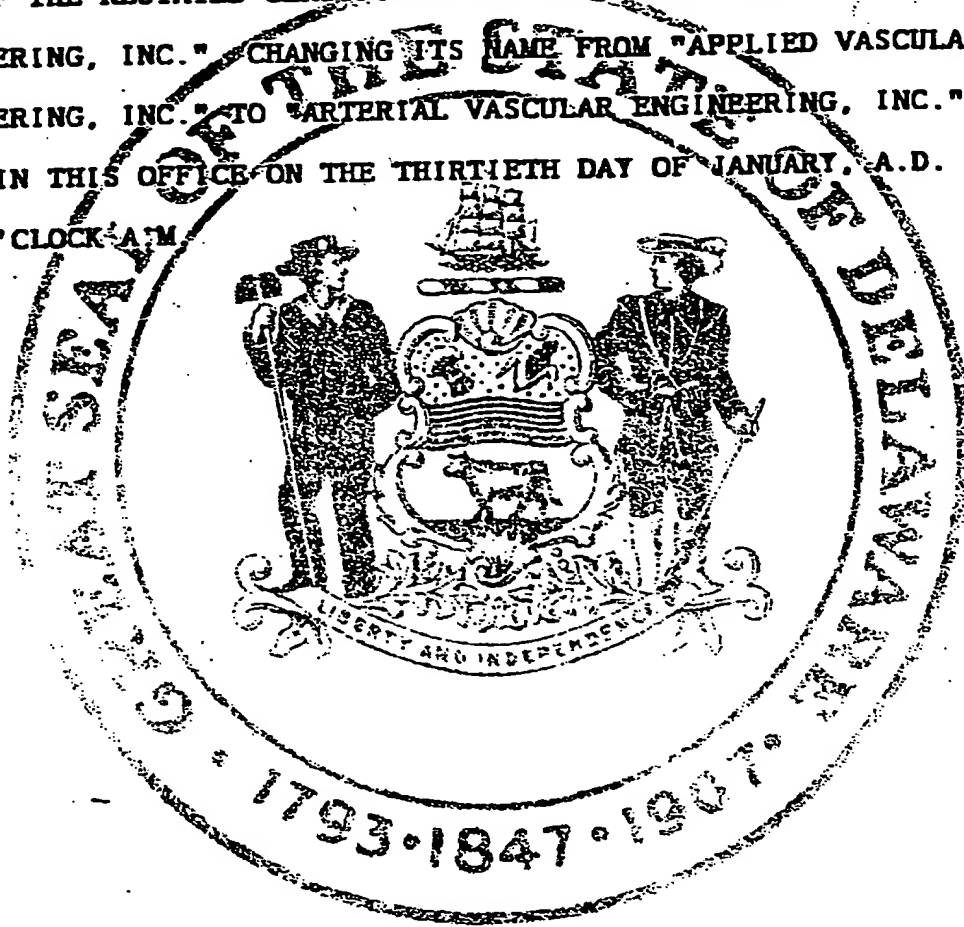
SERIAL NUMBER: 08619014
PATENT NUMBER:

FILING DATE: 03/20/1996
ISSUE DATE:

MAYA BENNETT, EXAMINER
ASSIGNMENT DIVISION
OFFICE OF PUBLIC RECORDS

Office of the Secretary of State

I, EDWARD J. FREEL, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE RESTATED CERTIFICATE OF "APPLIED VASCULAR ENGINEERING, INC." CHANGING ITS NAME FROM "APPLIED VASCULAR ENGINEERING, INC." TO "ARTERIAL VASCULAR ENGINEERING, INC.", FILED IN THIS OFFICE ON THE THIRTIETH DAY OF JANUARY, A.D. 1996, AT 9 O'CLOCK A.M.



Edward J. Freel, Secretary of State

2269660 8100

960762289

AUTHENTICATION: 7851810

DATE: 03-04-96

AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

I.

The name of this corporation is Arterial Vascular Engineering, Inc.

II.

The address of the registered office of the corporation in the State of Delaware is 1013 Centre Road, City of Wilmington, County of New Castle, and the name of the registered agent of the corporation in the State of Delaware at such address is The Prentice-Hall Corporation System, Inc.

III.

The purpose of this corporation is to engage in any lawful act or activity for which a corporation may be organized under the General Corporation Law of the State of Delaware.

IV.

A. This corporation is authorized to issue two classes of stock to be designated, respectively, "Common Stock" and "Preferred Stock." The total number of shares which the corporation is authorized to issue is Fifty Million Five Hundred Thousand (50,500,000) shares. Fifty Million (50,000,000) shares shall be Common Stock, each having a par value of one-tenth of one cent (\$.001). Five Hundred Thousand (500,000) shares shall be Preferred Stock, each having a par value of one-tenth of one cent (\$.001). Each outstanding share of Common Stock, par value \$.01, shall, upon filing of this Amended and Restated Certificate of Incorporation be reconstituted as 5.5 shares of Common Stock, par value \$.001. No fractional shares will be issued and, in lieu thereof, any holder of less than one share of Common Stock shall be entitled to receive cash for such holder's fractional share based on the fair market value of such stock as determined by the Company's Board of Directors.

B. The Preferred Stock may be issued from time to time in one or more series. The Board of Directors is hereby authorized, by filing a certificate (a "Preferred Stock Designation") pursuant to the Delaware General Corporation Law, to fix or alter from time to time the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations or restrictions of any wholly unissued series of Preferred Stock, and to establish from time to time the number of shares constituting any such series or any of them; and to increase or decrease the number of shares of any series subsequent to the issuance of shares of that series, but not below the number of shares of such series then outstanding. In case the number of shares of any series shall be decreased in accordance with the foregoing sentence, the shares constituting such decrease shall resume the status that they had prior to the adoption of the resolution originally fixing the number of shares of such series.

V.

For the management of the business and for the conduct of the affairs of the corporation, and in further definition, limitation and regulation of the powers of the corporation, of its directors and of its stockholders or any class thereof, as the case may be, it is further provided that:

A.

(1) The management of the business and the conduct of the affairs of the corporation shall be vested in its Board of Directors. The number of directors which shall constitute the whole Board of Directors shall be fixed exclusively by one or more resolutions adopted by the Board of Directors.

(2) Notwithstanding the foregoing provisions of this Article, each director shall serve until his successor is duly elected and qualified or until his death, resignation or removal. No decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.

Subject to the rights of the holders of any series of Preferred Stock to elect additional directors under specified circumstances, directors shall be elected at each annual meeting of stockholders. Each director shall serve until his successor is duly elected and qualified or until his death, resignation or removal. No decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.

(3) Following the closing of the initial public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, covering the offer and sale of the corporation's Common Stock to the public (the "Initial Public Offering"), and subject to the rights of the holders of any series of Preferred Stock, any vacancies on the Board of Directors resulting from death, resignation, disqualification, removal or other causes and any newly created directorships resulting from any increase in the number of directors, shall, unless the Board of Directors determines by resolution that any such vacancies or newly created directorships shall be filled by the stockholders and except as otherwise provided by law, be filled only by the affirmative vote of a majority of the directors then in office, even though less than a quorum of the Board of Directors, and not by the stockholders. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the director for which the vacancy was created or occurred and until such director's successor shall have been elected and qualified.

B.

(1) Subject to paragraph (h) of Section 43 of the Bylaws, the Bylaws may be altered or amended or new Bylaws adopted by the affirmative vote of at least eighty percent (80%) of the voting power of all of the then-outstanding shares of the Voting Stock. The Board of Directors shall also have the power to adopt, amend, or repeal Bylaws.

(2) The directors of the corporation need not be elected by written ballot unless the Bylaws so provide.

(3) Following the Initial Public Offering, no action shall be taken by the stockholders of the corporation except at an annual or special meeting of stockholders called in accordance with the Bylaws.

(4) Special meetings of the stockholders of the corporation may be called, for any purpose or purposes, by (i) the Chairman of the Board of Directors, (ii) the Chief Executive Officer, or (iii) the Board of Directors pursuant to a resolution adopted by a majority of the total number of authorized directors (whether or not there exist any vacancies in previously authorized directorships at the time any such resolution is presented to the Board of Directors for adoption), and shall be held at such place, on such date, and at such time as the Board of Directors shall fix.

(5) Advance notice of stockholder nominations for the election of directors and of business to be brought by stockholders before any meeting of the stockholders of the corporation shall be given in the manner provided in the Bylaws of the corporation.

VI.

A. A director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for any breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the Delaware General Corporation Law, or (iv) for any transaction from which the director derived an improper personal benefit. If the Delaware General Corporation Law is amended after approval by the stockholders of this Article to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director shall be eliminated or limited to the fullest extent permitted by the Delaware General corporation Law, as so amended.

B. Any repeal or modification of this Article VI shall be prospective and shall not affect the rights under this Article VI in effect at the time of the alleged occurrence of any act or omission to act giving rise to liability or indemnification.

VII.

A. The corporation reserves the right to amend, alter, change or repeal any provision contained in this Certificate of Incorporation, in the manner now or hereafter prescribed by statute, except as provided in paragraph B. of this Article VII, and all rights conferred upon the stockholders herein are granted subject to this reservation.

**AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF APPLIED VASCULAR ENGINEERING, INC.**

APPLIED VASCULAR ENGINEERING, INC., a corporation organized and existing under the General Corporation Law of the State of Delaware, does hereby certify as follows:

FIRST: The name of the corporation is **APPLIED VASCULAR ENGINEERING, INC.**

SECOND: The Certificate of Incorporation of the corporation was filed by the Secretary of State on July 30, 1991, under the name of Applied Vascular Engineering, Inc.

THIRD: The Amended and Restated Certificate of Incorporation of the corporation, in the form attached hereto as Exhibit A, has been duly adopted in accordance with the provisions of Sections 242 and 245 of the General Corporation Law of the State of Delaware by the Board of Directors of the corporation.

FOURTH: The Amended and Restated Certificate of Incorporation of the corporation, in the form attached hereto as Exhibit A, was approved by the written consent of a majority of the outstanding capital stock of the corporation in accordance with the provisions of Sections 242 and 245 of the General Corporation Law of the State of Delaware. Written consent has been provided, and written notice has been given, in accordance with Section 228 of the General Corporation Law of the State of Delaware. The corporation has one class of stock outstanding. The total number of outstanding shares of Common Stock of the corporation is four million eight hundred sixteen thousand nine hundred fifty-eight (4,816,958).

FIFTH: The Amended and Restated Certificate of Incorporation so adopted reads in full as set forth in Exhibit A attached hereto and hereby incorporated by reference.

IN WITNESS WHEREOF, **APPLIED VASCULAR ENGINEERING, INC.** has caused this Restated Certificate of Incorporation to be signed by its President and attested to by its Secretary this 29 day of January 1996.

APPLIED VASCULAR ENGINEERING, INC.

By: _____

Bradly A. Jendersee
Chief Executive Officer and President

ATTEST:



John D. Miller
Secretary

STATE OF DELAWARE
SECRETARY OF STATE
DIVISION OF CORPORATIONS
FILED 09:00 AM 01/30/1996
960028170 - 2269660



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

JUNE 20, 1996

PTAS

RECEIVED

JUL 01 1996



100166193A

FISH & NEAVE
NICOLA A. PISANO
1251 AVENUE OF THE AMERICAS
NEW YORK, NEW YORK 10020

FISH & NEAVE = PATENT DEPT.
REFERRED TO NAO
BY [Signature]

UNITED STATES PATENT AND TRADEMARK OFFICE
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 703-308-9723. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT DIVISION, BOX ASSIGNMENTS, NORTH TOWER BUILDING, SUITE 10C35, WASHINGTON, D.C. 20231.

RECORDATION DATE: 03/25/1996

REEL/FRAME: 7863/0672
NUMBER OF PAGES: 6

BRIEF: CHANGE OF NAME (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:
APPLIED VASCULAR ENGINEERING, INC. DOC DATE: 01/29/1996

ASSIGNEE:
ARTERIAL VASCULAR ENGINEERING, INC.
3624 WESTWIND BOULEVARD
SANTA ROSA, CALIFORNIA 95403

SERIAL NUMBER: 08172420
PATENT NUMBER:

FILING DATE: 12/22/1993
ISSUE DATE:

SERIAL NUMBER: 08471738
PATENT NUMBER: 5,891,190

FILING DATE: 06/06/1995
ISSUE DATE: 4/6/99

SERIAL NUMBER: 08465842
PATENT NUMBER: 5,800,509

FILING DATE: 06/06/1995
ISSUE DATE: 9/1/98

SERIAL NUMBER: 08326023
PATENT NUMBER:

FILING DATE: 10/19/1994
ISSUE DATE:

ORIG/COPY
SENT TO 7/1/96
CALIFORNIA
BY [Signature]

7863/0672 PAGE 2

SERIAL NUMBER: 08478192
PATENT NUMBER:

SERIAL NUMBER: 08451270
PATENT NUMBER:

SERIAL NUMBER: 08326031
PATENT NUMBER:

SERIAL NUMBER: 08562138
PATENT NUMBER:

SERIAL NUMBER: 08568543
PATENT NUMBER:

SERIAL NUMBER: 08568834
PATENT NUMBER:

SERIAL NUMBER: 07398180
PATENT NUMBER: 5292331

FILING DATE: 06/07/1995
ISSUE DATE:

FILING DATE: 05/30/1995
ISSUE DATE:

FILING DATE: 10/19/1994
ISSUE DATE:

FILING DATE: 11/22/1995
ISSUE DATE:

FILING DATE: 12/07/1995
ISSUE DATE:

FILING DATE: 12/07/1995
ISSUE DATE:

FILING DATE: 08/24/1989
ISSUE DATE: 03/08/1994

JERYL MCDOWELL, EXAMINER
ASSIGNMENT DIVISION
OFFICE OF PUBLIC RECORDS

ECOI

04-03-1996

ET

U.S. DEPARTMENT OF COMMERCE
Patent and Trademark Office

Tab settings 000 ▼

3-25-96



100166193

ed original documents or copy thereof.

To the Honorable Commissioner of Patents

1. Name of conveying party(ies):

Applied Vascular Engineering, Inc.

Additional name(s) of conveying party(ies) attached? ☐ Yes ☒ No

3. Nature of conveyance:

☐ Assignment

☐ Merger

☐ Security Agreement

☒ Change of Name

☐ Other

Execution Date: January 29, 1996

2. Name and address of receiving party(ies)

Name: Arterial Vascular Engineering, Inc.

Internal Address:

Street Address: 3621 Westwind Boulevard

City: Santa Rosa State: CA ZIP: 95403

Additional name(s) & address(es) attached? ☐ Yes ☒ No

4. Application number(s) or patent number(s):

If this document is being filed together with a new application, the execution date of the application is:

A. Patent Application No.(s)

08/172,420; 08/471,738; 08/465,842;
08/326,023; 08/478,192; 08/451,270;
08/326,031; 08/562,138; 08/568,543;
08/568,834

B. Patent No.(s)

5,292,331

Additional numbers attached? ☐ Yes ☒ No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: Nicola A. Pisano

Internal Address: c/o FISH & NEAVE

Street Address: 1251 Avenue of the Americas

City: New York State: NY ZIP: 10020

6. Total number of applications and patents involved: 11

7. Total fee (37 CFR 3.41).....\$ 440.00

☒ Enclosed

☐ Authorized to be charged to deposit account

8. Deposit account number:

06-1075

(Attach duplicate copy of this page if paying by deposit account)

060 JS 03/29/96 08172420

DO NOT USE THIS SPACE

1 581

440.00 CK

9. Statement and signature.

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

Nicola A. Pisano

Name of Person Signing

Signature

3-16-96

Date

Total number of pages including cover sheet, attachments, and document: 6

Mail documents to be recorded with required cover sheet information to:
Commissioner of Patents & Trademarks, Box Assignments
Washington D.C. 20231

RECORDATION FORM COVER SHEET
PATENTS ONLY

U.S. DEPARTMENT OF COMMERCE
Patent and Trademark Office

Tab settings 000 ▼

To the Honorable Commissioner of Patents and Trademarks: Please record the attached original documents or copy thereof.

1. Name of conveying party(ies):

Applied Vascular Engineering, Inc.

Additional name(s) of conveying party(ies) attached? ☐ Yes ☒ No

3. Nature of conveyance:

☐ Assignment

☐ Merger

☐ Security Agreement

☒ Change of Name

☐ Other _____

Execution Date: January 29, 1996

2. Name and address of receiving party(ies)

Name: Arterial Vascular Engineering
Inc

Internal Address: _____

Street Address: 3621 Westwind Boulevard

City: Santa Rosa State: CA ZIP: 9540

Additional name(s) & address(es) attached? ☐ Yes ☒ No

4. Application number(s) or patent number(s):

If this document is being filed together with a new application, the execution date of the application is: _____

A. Patent Application No.(s)

08/172,420; 08/471,738; 08/465,842;
08/326,023; 08/478,192; 08/451,270;
08/326,031; 08/562,138; 08/568,543;
08/568,834

B. Patent No.(s)

5,292,331

Additional numbers attached? ☐ Yes ☒ No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: Nicola A. Pisano

Internal Address: c/o FISH & NEAVE

Street Address: 1251 Avenue of the
Americas

City: New York State: NY ZIP: 10020

6. Total number of applications and patents involved: 11

7. Total fee (37 CFR 3.41).....\$ 440.00

☒ Enclosed

☐ Authorized to be charged to deposit account

8. Deposit account number:

06-1075

(Attach duplicate copy of this page if paying by deposit account)

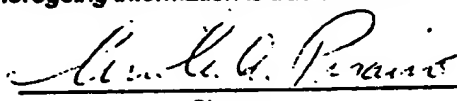
DO NOT USE THIS SPACE

9. Statement and signature.

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

Nicola A. Pisano

Name of Person Signing



Signature

3-16-96

Date

6

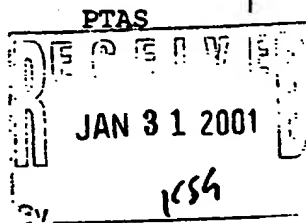
Total number of pages including cover sheet, attachments, and document:



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

JANUARY 24, 2001

MEDTRONIC AVE INC.
CATHERINE C. MARESH
IP LEGAL
3576 UNOCAL PLACE
SANTA ROSA, CA 95403



101526093A

UNITED STATES PATENT AND TRADEMARK OFFICE
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 703-308-9723. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT DIVISION, BOX ASSIGNMENTS, CG-4, 1213 JEFFERSON DAVIS HWY, SUITE 320, WASHINGTON, D.C. 20231.

RECORDATION DATE: 11/14/2000

REEL/FRAME: 011258/0053
NUMBER OF PAGES: 6

BRIEF: CHANGE OF NAME (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:

ARTERIAL VASCULAR ENGINEERING,
INC.

DOC DATE: 01/28/1999

ASSIGNEE:

MEDTRONIC AVE, INC.
3576 UNICAL PLACE
SANTA ROSA, CALIFORNIA 94928

SERIAL NUMBER: 09287216

PATENT NUMBER:

FILING DATE: 04/05/1999

ISSUE DATE:

DOCKETED

CPI 154

RED BOOK

2nd Review

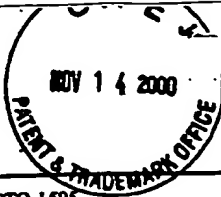
SEDLEY PYNE, PARALEGAL
ASSIGNMENT DIVISION
OFFICE OF PUBLIC RECORDS

NOTE: CHECK TO HAVE YOUR DOCUMENTS AND DRIVERS

NOTE: CHECK TO HAVE YOUR DOCUMENTS AND DRIVERS

NOTE: CHECK TO HAVE YOUR DOCUMENTS AND DRIVERS

Re
11-14-00



11-24-2000

ocket No. P106 DIV 3 C



FORM PTO-1595
(Rev. 6-93)

101526093

Department of Commerce
and Trademark Office

To the Honorable Asst. Commissioner for Patents. Please record the attached original documents or copy thereof.

1. Name of Conveying Party(ies):
Arterial Vascular Engineering, Inc.

Additional name(s) of conveying parties attached?
☐ Yes ☐ No

3. Nature of conveyance:

Assignment ☐ Merger
☐ Security Agreement ☒ Change of Name
☐ Other:
Execution Date: January 28, 1999

2. Name and address of receiving party (ies):

Name: MEDTRONIC AVE, INC.

Internal Address:

Street Address: 3576 Unocal Place

City: Santa Rosa State: CA ZIP: 94928

Additional names and addresses attached?

☐ Yes ☐ No

4. Application Number(s) or Patent Number(s):
U.S. Application Serial No: 09/287,216

If this document is being filed together with a new application, the execution date of the application is:

A. Patent Application No(s):

B. Patent No(s):

Additional numbers attached? ☐ Yes ☐ No

5. Names and address of party to whom correspondence concerning document should be mailed:

Name: IP Legal
Medtronic AVE Inc.
3576 Unocal Place
Santa Rosa, CA. 95403
(707) 541-3155

6. Total number of applications and patents involved: 1

7. Total fee (37 CFR 3.41): \$40.00
☐ Enclosed ☒ Charge Fees to Deposit Account
☒ Charge any additional fees associated with this paper or during the pendency of this application, or credit any overpayment, to deposit account.

8. Deposit account number: 01-2525

DO NOT USE THIS SPACE

9. Statement and signature:

To the best of my knowledge and belief, the foregoing is true and correct and any attached copy is a true of copy of the original document.

Catherine C. Maresh
Name of Person Signing

Signature

November 9, 2000
Date

Att Reg. No 35,268

Total number of pages including cover sheet, attachments and document 5

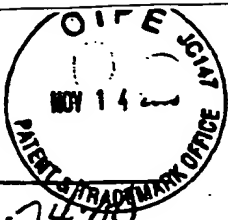
10. Change Correspondence Address to that of Part 5? ☒ Yes ☐ No

OMB No. 0651-0011 (exp. 4/94)

Do not detach this portion

Mail documents to be recorded with required cover to:

Asst. Commissioner for Patents
Box; Assignments
Washington, D.C. 20231



08-28-2000

Docket No. P106 DIV 3 C

FORM PTO-1595
(Rev. 6-93)

101444379

Department of Commerce
Patent and Trademark Office

To the Honorable Asst. Commissioner for Patents. Please record the attached original documents or copy thereof.

1. Name of Conveying Party(ies):
Arterial Vascular Engineering, Inc.

Additional name(s) of conveying parties attached?

☐ Yes ☐ No

3. Nature of conveyance:

☐ Assignment
☐ Security Agreement
☐ Other:
Execution Date:☐ Merger
☒ Change of Name

2. Name and address of receiving party (ies):

Name: MEDTRONIC AVE, INC.

Internal Address:

Street Address: 3576 Unocal Place

City: Santa Rosa State: CA ZIP: 95928

Additional names and addresses attached?

☐ Yes ☐ No4. Application Number(s) or Patent Number(s):
U.S. Application Serial No: 09/287,216

If this document is being filed together with a new application, the execution date of the application is:

A. Patent Application No(s):

B. Patent No(s):

Additional numbers attached? ☐ Yes ☐ No5. Names and address of party to whom correspondence
concerning document should be mailed:Name: IP Legal
Medtronic AVE Inc.
3576 Unocal Place
Santa Rosa, CA. 95403
(707) 541-3155

6. Total number of applications and patents involved: 1

7. Total fee (37 CFR 3.41): \$40.00

☐ Enclosed ☒ Charge Fees to Deposit Account
☒ Charge any additional fees associated with this paper
or during the pendency of this application, or credit
any overpayment, to deposit account.

8. Deposit account number: 01-2525

DO NOT USE THIS SPACE

9. Statement and signature:

*To the best of my knowledge and belief, the foregoing is true and correct and any attached copy is a true of copy of the original document.*Catherine C. Maresh
Name of Person Signing

Signature

Date

Att Reg. No 35,268

Total number of pages including cover sheet, attachments and document 5

10. Change Correspondence Address to that of Part 5? ☒ Yes ☐ No

OMB No. 0651-0011 (exp. 4/94)

Do not detach this portion

Mail documents to be recorded with required cover to:

00000166 012525 09287216

Asst. Commissioner for Patents
Box; Assignments
Washington, D.C. 202311/25/2000 DNGUYEN
FC:581

40.00 CH

State of Delaware
Office of the Secretary of State

PAGE 1

I, EDWARD J. FREEL, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF MERGER, WHICH MERGES:

"MAV MERGER CORP.", A DELAWARE CORPORATION,
WITH AND INTO "ARTERIAL VASCULAR ENGINEERING, INC." UNDER THE NAME OF "MEDTRONIC AVE, INC.", A CORPORATION ORGANIZED AND EXISTING UNDER THE LAWS OF THE STATE OF DELAWARE, AS RECEIVED AND FILED IN THIS OFFICE THE TWENTY-EIGHTH DAY OF JANUARY, A.D. 1999, AT 3 O'CLOCK P.M.



2269660 8100M

991196713



Edward J. Freel, Secretary of State

AUTHENTICATION:

9756414

DATE:

05-20-99

FROM RICHARDS, LAYTON & FINGER #10

(WED) 1.28'98 15:03/ST. 15:03

STATE OF DELAWARE
DIVISION OF CORPORATIONS
FILED 03:00 PM 01/28/1999
991035130 - 2269660



**CERTIFICATE OF MERGER
OF
MAV MERGER CORP.
INTO
ARTERIAL VASCULAR ENGINEERING, INC.**

The undersigned corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware,

DOES HEREBY CERTIFY:

FIRST, That the name and state of incorporation of each of the constituent corporations of the merger is as follows:

<u>Name</u>	<u>State of Incorporation</u>
Arterial Vascular Engineering, Inc.	Delaware
MAV Merger Corp.	Delaware

SECOND: That an Agreement and Plan of Merger between the parties to the merger has been approved, adopted, certified, executed and acknowledged by each of the constituent corporations in accordance with the requirements of subsection (c) of Section 251 of the General Corporation Law of the State of Delaware.

THIRD: That the name of the surviving corporation of the merger is Arterial Vascular Engineering, Inc., which upon the merger will change its name to "Medtronic AVE, Inc."

FOURTH: That the restated certificate of incorporation of the surviving corporation shall, as a result of the merger, be amended and restated in its entirety to read as set forth on Exhibit A hereto.

FIFTH: That the executed Agreement and Plan of Merger is on file at an office of the surviving corporation. The address of such office of the surviving corporation is 3576 Unocal Place, Santa Rosa, California 95403.

SIXTH: That a copy of the Agreement and Plan of Merger will be furnished by the surviving corporation, on request and without cost, to any stockholder of any constituent corporation.

ARTERIAL VASCULAR ENGINEERING, INC.

By:

Lawrence J. Fassler

Vice President of Legal Affairs, General Counsel and
Secretary

**AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
ARTERIAL VASCULAR ENGINEERING, INC.**

ARTICLE 1 - NAME

The name of the corporation shall be Medtronic AVE, Inc.

ARTICLE 2 - REGISTERED OFFICE AND AGENT

The registered office of the corporation in the State of Delaware is 1209 Orange Street, in the City of Wilmington, County of New Castle, Delaware, 19801. The name of its registered agent at such address is The Corporation Trust Company.

ARTICLE 3 - PURPOSES

The nature of the business or purposes to be conducted or promoted by the corporation is to engage in any lawful acts and activities for which corporations may be organized under the General Corporation Law of Delaware.

ARTICLE 4 - STOCK

The aggregate number of shares the corporation has authority to issue shall be 2,500 shares of Common Stock, \$.01 par value. Holders of Common Stock shall be entitled to one vote for each share of Common Stock held of record.

ARTICLE 5 - RIGHTS OF STOCKHOLDERS

5.1) No Preemptive Rights. No holder of shares of the corporation of any class now or hereafter authorized has any preferential or preemptive right to subscribe for, purchase or receive any shares of the corporation of any class now or hereafter authorized, or any options or warrants for such shares, which may at any time be issued, sold or offered for sale by the corporation.

5.2) No Cumulative Voting Rights. No holder of shares of the corporation of any class now or hereafter authorized shall be entitled to cumulative voting.

ARTICLE 6 - MEETINGS AND BOOKS

6.1) Meetings of Stockholders and Election of Directors. Meetings of stockholders may be held within or outside the State of Delaware, as the Bylaws may provide. Elections of directors need not be by written ballot unless and except to the extent that the Bylaws so provide.

6.2) Corporate Books. The books of the corporation may be kept within or (subject to any provision contained in the statutes) outside the State of Delaware at such place or places as may be designated from time to time by the Board of Directors or in the Bylaws of the corporation.

ARTICLE 7 - LIMITATION OF DIRECTOR LIABILITY

7.1) Limitation of Liability. A director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for any breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the Delaware General Corporation Law, or (iv) for any transaction from which the director derived an improper personal benefit. If the Delaware General Corporation Law is amended after approval by the stockholders of this Article to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director shall be eliminated or limited to the fullest extent permitted by the Delaware General Corporation Law, as so amended.

7.2) Amendment of this Article. Any repeal or modification of this Article 7 shall be prospective and shall not affect the rights under this Article 7 in effect at the time of the alleged occurrence of any act or omission to act giving rise to liability or indemnification.

ARTICLE 8 - BYLAWS

The Board of Directors is expressly authorized to make and alter Bylaws of this corporation, subject to the power of the stockholders to change or repeal such Bylaws and subject to any other limitations on such authority provided by the General Corporation Law of Delaware.

2200631-8



US006344053B1

(12) **United States Patent**
Boneau

(10) **Patent No.:** **US 6,344,053 B1**
(45) **Date of Patent:** **Feb. 5, 2002**

(54) **ENDOVASCULAR SUPPORT DEVICE AND METHOD**

- (75) **Inventor:** Michael D. Boneau, Campbell, CA (US)
(73) **Assignee:** Medtronic AVE, Inc., Santa Rosa, CA (US)
(*) **Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 45 days.

(21) **Appl. No.:** 09/287,216
(22) **Filed:** Apr. 5, 1999

Related U.S. Application Data

- (60) Continuation of application No. 08/471,738, filed on Jun. 6, 1995, now Pat. No. 5,891,190, which is a division of application No. 08/172,420, filed on Dec. 22, 1993, now abandoned, which is a division of application No. 07/398,180, filed on Aug. 24, 1999, now Pat. No. 5,292,331.
(51) **Int. Cl.**⁷ A61F 2/04
(52) **U.S. Cl.** 623/1.11; 606/198
(58) **Field of Search** 623/1.11, 1.15; 606/198

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,070,073 A 2/1937 Walton
2,701,559 A 2/1955 Cooper
2,854,982 A 10/1958 Pagano

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

AU A-23784/88 4/1989
AU B-53198/94 8/1989
AU B-61333/90 8/1989
DE 2410933 9/1974

(List continued on next page.)

OTHER PUBLICATIONS

Charnsangavej C., M.D., et al., "A New Expandable Metallic Stent for Dilation of Stenotic Tubular Structures: Experimental and Clinical Evaluation," *Houston Medical Journal* 1987; 3: 41-52.
Culverwell M., "Angioplasty Stents May Prevent Restenosis," *Carcio* 1987; Jan.; 11-13.
Palmaz J.C., M.D., et al., "Atherosclerotic Rabbit Aortas: Expandable Intraluminal Grafting," *Radiology* 1986; 3: 723-726.
Schatz R., M.D., et al., "Balloon-expandable intracoronary stents in the adult dog," *Circulation* 1987; 76: 450-457.
Palmaz J.C., "Die intraluminale Sten-Implantation nach Palmaz," *Radiologe* 1987; 11: 560-563.
Roubin G., et al., "Early and late results of intracoronary arterial stenting after coronary angioplasty in dogs," *Circulation* 1987; 4: 891-897.
Fallone B.G., PhD., "Elastic Characteristics of the Self-expanding Metallic Stents," *Investigative Radiology* 1988; 23: 370-376.

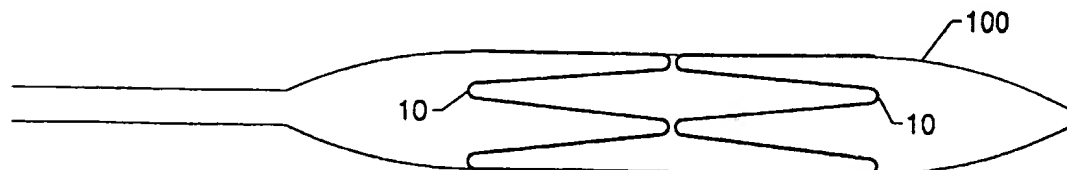
(List continued on next page.)

Primary Examiner—David H. Willse
Assistant Examiner—Suzette J. Jackson
(74) **Attorney, Agent, or Firm**—Sierne, Kessler, Goldstein & Fox, P.L.L.C.

(57) **ABSTRACT**

An endovascular support device for treatment of chronic restenosis or other vascular narrowing is disclosed together with a method of manufacture and a method for delivering a plurality of such devices to an affected area of a vessel. In a preferred embodiment, the endovascular support device comprises a unitary wire-like structure configured to form a plurality of upper and lower peaks which may be compressed for delivery to an affected area of a coronary or peripheral vessel in a human, and then expanded to maintain a passageway through the vessel.

30 Claims, 4 Drawing Sheets



U.S. PATENT DOCUMENTS

2,854,983 A	10/1958	Baskin	4,586,505 A	5/1986	Sisson et al.
3,105,492 A	10/1963	Jeckel	4,604,762 A	8/1986	Robinson
3,155,095 A	11/1964	Brown	4,617,932 A	10/1986	Kornberg
3,284,762 A	11/1966	Kompanek	4,619,246 A	10/1986	Molgaard-Nielsen et al.
3,334,629 A	8/1967	Cohn	4,619,261 A	10/1986	Guerriero
3,526,005 A	9/1970	Bokros et al.	4,641,653 A	2/1987	Rockey
3,540,431 A	11/1970	Mobin-Uddin	4,643,184 A	2/1987	Mobin-Uddin
3,562,820 A	2/1971	Braun	4,647,416 A	3/1987	Seiler, Jr. et al.
3,599,641 A	8/1971	Sheridan	4,649,922 A	3/1987	Wiktor 128/344
3,657,744 A	4/1972	Ersek	4,649,922 C1 *	3/1987	Wiktor 128/344
3,713,175 A	1/1973	Weisman	4,650,466 A	3/1987	Luther
3,714,671 A	2/1973	Edwards et al.	4,655,771 A	4/1987	Wallsten
3,774,596 A	11/1973	Cook	4,660,559 A	4/1987	McGregor et al.
3,834,394 A	9/1974	Hunter et al.	4,660,560 A	4/1987	Klein
3,858,441 A	1/1975	Comeau et al.	4,665,918 A	5/1987	Garza et al.
3,868,956 A	3/1975	Alfidi et al.	4,670,734 A	6/1987	Caddock
3,874,388 A	4/1975	King et al.	4,673,409 A	6/1987	Van Kampen
3,882,845 A	5/1975	Bucalo	4,676,241 A	6/1987	Webb et al.
3,889,685 A	6/1975	Miller, Jr. et al.	4,680,031 A	7/1987	Alonso
3,893,344 A	7/1975	Dantlgraber et al.	4,681,110 A	7/1987	Wiktor
3,894,974 A	7/1975	Hunter et al.	4,699,611 A	10/1987	Bowden
3,952,747 A	4/1976	Kimmell, Jr.	4,704,126 A	11/1987	Baswell et al.
3,968,800 A	7/1976	Vilasi	4,705,517 A	11/1987	DiPisa, Jr.
4,038,702 A	8/1977	Sawyer	4,706,671 A	11/1987	Weinrib
4,047,252 A	9/1977	Liebig et al.	4,710,181 A	12/1987	Fuqua
4,056,854 A	11/1977	Boretos et al.	4,723,549 A	2/1988	Wholey et al.
4,061,134 A	12/1977	Samuels et al.	4,731,054 A	3/1988	Billeter et al.
4,065,816 A	1/1978	Sawyer	4,733,665 A	3/1988	Palmaz
4,076,285 A	2/1978	Martinez	4,739,762 A *	4/1988	Palmaz 128/343
4,080,706 A	3/1978	Heilman et al.	4,740,207 A	4/1988	Kreamer
4,105,022 A	8/1978	Antoshkiw et al.	4,760,849 A	8/1988	Kropf
4,106,129 A	8/1978	Carpentier et al.	4,762,128 A	8/1988	Rosenbluth
4,140,126 A	2/1979	Choudhury	4,767,418 A	8/1988	Deininger et al.
4,159,719 A	7/1979	Haerr	4,768,507 A	9/1988	Fischell et al.
4,183,102 A	1/1980	Guiset	4,771,773 A	9/1988	Kropf
4,190,909 A	3/1980	Ablaza	4,775,426 A	10/1988	Murley et al.
4,195,637 A	4/1980	Gruntzig et al.	4,776,337 A	10/1988	Palmaz
4,198,982 A	4/1980	Fortner et al.	4,787,899 A	11/1988	Lazarus
4,214,587 A	7/1980	Sakura	4,793,348 A	12/1988	Palmaz
4,276,132 A	6/1981	Fettel et al.	4,794,928 A	1/1989	Kletschka
4,295,464 A	10/1981	Shihata	4,795,458 A	1/1989	Regan
4,299,226 A	11/1981	Banka	4,800,882 A	1/1989	Gianturco
4,300,244 A	11/1981	Bokros	4,813,925 A	3/1989	Anderson, Jr. et al.
4,313,231 A	2/1982	Koyamada	4,830,003 A	5/1989	Wolff et al.
4,319,363 A	3/1982	Ketharanathan	4,842,575 A	6/1989	Hoffman, Jr. et al.
4,323,994 A	4/1982	Coogler	4,848,343 A	7/1989	Wallsten et al.
4,328,811 A	5/1982	Fogarty	4,856,516 A	8/1989	Hillstead
4,338,942 A	7/1982	Fogarty	4,869,714 A	9/1989	Deininger et al.
4,340,046 A	7/1982	Cox	4,870,966 A	10/1989	Dellon et al.
4,343,048 A	8/1982	Ross et al.	4,875,480 A	10/1989	Imbert
4,343,049 A	8/1982	Fettel et al.	4,877,030 A	10/1989	Beck et al.
4,390,599 A	6/1983	Broyles	4,878,906 A	11/1989	Lindemann et al.
4,402,307 A	9/1983	Hanson et al.	4,886,062 A	12/1989	Wiktor
4,403,612 A	9/1983	Fogarty	4,892,539 A	1/1990	Koch
4,733,665 C1	1/1984	Palmaz	4,892,541 A	1/1990	Alonso
4,448,195 A	5/1984	LeVeen et al.	4,893,623 A	1/1990	Rosenbluth
4,479,497 A	10/1984	Fogarty et al.	4,902,289 A	2/1990	Yannas
4,483,340 A	11/1984	Fogarty et al.	4,907,336 A	3/1990	Gianturco
4,493,711 A	1/1985	Chin et al.	4,913,141 A	4/1990	Hillstead
4,494,531 A	1/1985	Gianturco	4,922,905 A	5/1990	Strecker
4,503,569 A	3/1985	Dotter	4,923,464 A	5/1990	DiPisa, Jr.
4,512,338 A	4/1985	Balko et al.	4,950,227 A	8/1990	Savin et al.
4,531,933 A	7/1985	Norton et al.	4,954,126 A	9/1990	Wallsten
4,550,447 A	11/1985	Seiler, Jr. et al.	4,969,458 A	11/1990	Wiktor
4,553,545 A	11/1985	Maass et al.	4,969,890 A	11/1990	Sugita et al.
4,560,374 A	12/1985	Hammerslag	4,986,831 A	1/1991	King et al.
4,562,596 A	1/1986	Kornberg	4,990,155 A	2/1991	Wilkoff
4,572,186 A	2/1986	Gould et al.	4,994,032 A	2/1991	Sugiyama et al.
4,577,631 A	3/1986	Kreamer	4,994,071 A	2/1991	MacGregor
4,580,568 A *	4/1986	Gianturco 623/1.15	4,994,077 A	2/1991	Dobben
			4,998,539 A	3/1991	Delsanti

4,998,923 A	3/1991	Samson et al.	5,800,509 A	9/1998	Boneau	
5,002,560 A	3/1991	Machold et al.	4,739,762 C1	10/1998	Palmaz	606/108
5,007,926 A	4/1991	Derbyshire	5,879,382 A	3/1999	Boneau	
5,015,253 A	5/1991	Macgregor	5,891,190 A	4/1999	Boneau	623/1.11
5,019,085 A	5/1991	Hillstead	5,902,332 A	5/1999	Schatz	
5,019,090 A	5/1991	Pinchuk				
5,026,377 A	6/1991	Burton et al.				
5,034,001 A	7/1991	Garrison et al.				
5,035,706 A	7/1991	Giantureo et al.				623/1.15
5,037,377 A	8/1991	Alonso				
5,037,392 A	8/1991	Hillstead				
5,037,427 A	8/1991	Harada et al.				
5,041,126 A	8/1991	Gianturco				
5,059,211 A	10/1991	Stack et al.				
5,061,275 A	10/1991	Wallsten et al.				
5,062,829 A	11/1991	Pryor et al.				
5,064,435 A	11/1991	Porter				
5,071,407 A	12/1991	Termin et al.				
5,078,726 A	1/1992	Kreamer				
5,078,736 A	1/1992	Behl				
5,084,065 A	1/1992	Weldon et al.				
5,089,005 A	2/1992	Harada				
5,089,006 A	2/1992	Stiles				
5,092,877 A	3/1992	Pinchuk				
5,102,417 A	4/1992	Palmaz				
5,104,399 A	4/1992	Lazarus				
5,104,404 A	4/1992	Wolff				
5,108,416 A	4/1992	Ryan et al.				
5,108,417 A	4/1992	Sawyer				
5,122,154 A	6/1992	Rhodes				
5,123,917 A	6/1992	Lee				
5,133,732 A	7/1992	Wiktor				
5,135,536 A	8/1992	Hillstead				
5,163,958 A	11/1992	Pinchuk				
5,192,307 A	3/1993	Wall				
5,195,984 A	3/1993	Schatz				
5,201,901 A	4/1993	Harada				
RE34,327 E	7/1993	Kreamer				
5,226,913 A	7/1993	Pinchuk				
5,236,447 A	8/1993	Kubo et al.				
5,266,073 A	11/1993	Wall				
5,275,622 A	1/1994	Lazarus				
5,282,824 A	2/1994	Gianturco				
5,282,848 A	2/1994	Schmitt				
5,292,331 A	3/1994	Boneau				606/198
5,306,286 A	4/1994	Stack et al.				
5,314,444 A	5/1994	Gianturco				
5,342,348 A	8/1994	Kaplan				
5,382,261 A	1/1995	Palmaz				
5,383,892 A	1/1995	Cardon et al.				
5,397,345 A	3/1995	Lazarus				
5,421,955 C1	6/1995	Lau et al.				
5,443,496 A	8/1995	Schwartz et al.				
5,507,767 A	4/1996	Maeda et al.				
5,507,768 A	4/1996	Lau et al.				
5,507,771 A	4/1996	Gianturco				
4,954,126 C1	5/1996	Wallsten				
5,527,336 A	6/1996	Rosenbluth et al.				
5,549,635 A	8/1996	Solar				623/1.11
4,655,771 C1	9/1996	Wallsten				
5,556,413 A	9/1996	Lam				
5,562,728 A	10/1996	Lazarus				
5,569,295 A	10/1996	Lam				623/1.11
5,591,197 A	1/1997	Orth et al.				
5,591,198 A	1/1997	Boyle et al.				623/1.11
5,618,299 A	4/1997	Khosravi et al.				
5,618,301 A	4/1997	Hauenstein				
5,653,727 A	8/1997	Wiktor				
5,662,700 A	9/1997	Lazarus				
5,669,936 A	9/1997	Lazarus				
5,674,278 A	10/1997	Boneau				

FOREIGN PATENT DOCUMENTS

DE	3205942 A1	9/1983
DE	3640745 A1	6/1987
DE	690 29 114 T 2	3/1997
DK	EP 0417928 T3	12/1996
EP	0 183 372	6/1986
EP	0 177 330	9/1986
EP	0 274 846 A1	7/1988
EP	0 282 175 A1	9/1988
EP	0 312 852	4/1989
EP	0 417 928	8/1989
EP	0 417 928 B1	3/1991
EP	0 423 916 A1	4/1991
EP	0 483 372 A1	5/1992
EP	0 540 290 A2	5/1993
EP	0 729 767 A1	9/1996
GB	1205743	9/1970
GB	2 092 894 A	8/1982
GB	2 135 585 A	9/1984
JP	60-500520	4/1985
JP	61-41444	2/1986
JP	1-145076	7/1989
RU	660689	5/1979
SU	764684	9/1980
SU	1457921	2/1989
WO	WO 83/03752	11/1983
WO	WO 89/01798	3/1989

OTHER PUBLICATIONS

- Palmaz J.C., et al., "Expandable Intrahepatic Portacaval Shunt Stents: Early Experience in the Dog," *AJR* 1985; 145: 821-825.
- Palmaz J.C., et al., "Expandable Intrahepatic Portacaval Shunt Stents in Dogs with Chronic Portal Hypertension," *AJR* 1986; 147: 1251-1254.
- Palmaz J.C., M.D., "Expandable Intraluminal Graft: A Preliminary Study," *Radiology* 1985; 156: 73-77.
- Palmaz J.C., M.D., "Expandable intraluminal vascular graft: A feasibility study," *Surgery* 1986; 2: 199-205.
- Frimberger E., "Expanding Spiral—A New Type of Prosthesis for the Palliative Treatment of Malignant Esophageal Stenoses," *Endoscopy* 1983; 15: 213-214.
- Duprat G., Jr., M.D., et al., "Flexible Balloon-expanded Sten for Small Vessels," *Radiology* 1987; 162: 276-278.
- Rosch J., M.D., et al., "Gianturco Expandable Wire Stents in the Treatment of Superior Vena Cava Syndrome Recurring After Maximum-Tolerance Radiation," *Cancer* 1987; 60:1243-1246.
- Mullins C.E., M.D., et al., "Implantation of balloon-expandable intravascular grafts by catheterization in pulmonary arteries and systemic veins," *Circulation* 1988; 77: 188-199.
- Papanicolaou N., et al., "Insertion of a Biliary Endoprosthesis Using a Balloon Dilation Catheter," *Gastrointestinal Radiology* 1985; 10: 394-396.
- Sigwart U., M.D., et al., "Intravascular Stents To Prevent Occlusion And Restenosis After Transluminal Angioplasty," *The New England Journal of Medicine* 1987; 316: 701-706.
- Rosch J., et al., "Modified Gianturco Expandable Wire Stents In Experimental and Clinical Use," *CIRSE* 1987; 31: 100-103.

- Uchida B.T., et al., "Modifications of Gianturco Expandable Wire Stents," *AJR* 1988; 150: 1185-1187.
- Cragg A., M.D., et al., "Nonsurgical Placement of Arterial Endoprostheses: A New Technique Using Nitinol Wire," *Radiology* 1983; 147: 261-263.
- Palmaz J.C., M.D., et al., "Normal and Stenotic Renal Arteries: Experimental Balloon-expandable Intraluminal Stenting," *Radiology* 1987; Sep. 164 : 705-708.
- Maass D., et al., "Radiological Follow-up of Transluminally Inserted Vascular Endoprostheses: An Experimental Study Using Expanding Spirals," *Radiology* 1984; 152: 659-663.
- Rousseau H., M.D., et al., "Self-expanding Endovascular Prosthesis: An Experimental Study," *Radiology* 1987; Sep. 164: 709-714.
- Duprat G. Jr., M.D., et al., "Self-expanding Metallic Stents for Small Vessels: An Experimental Evaluation," *Radiology* 1987; 162: 469-472.
- Roland M., M.D., "Spiral Teflon Stent for Tuboplasty Involving Fimbria," *Obstetrics Gynecology* 1970; 36: 359-362.
- Charnsangavej C., M.D., et al., "Stenosis of the Vena Cava: Preliminary Assessment of Treatment with Expandable Metallic Stents," *Radiology* 1986; Nov. 161: 295-298.
- Wallace M.J., et al., "Tracheobronchial Tree: Expandable Metallic Stents Used in Experimental and Clinical Applications," *Radiology* 1986; 158: 309-312.
- Balko A., M.D., et al., "Transfemoral Placement of Intraluminal Polyurethane Prosthesis for Abdominal Aortic Aneurysm," *Journal of Surgical Research* 1986; 40: 305-309.
- Dotter C.T., M.D., et al., "Transluminal Expandable Nitinol Coil Stent Grafting: Preliminary Report," *Radiology* 1983; 147: 259-260.
- Strecker E.P., et al., "A New Vascular Balloon-expandable Prosthesis—Experimental Studies and First Clinical Results," *Journal of Interventional Radiology* 1988; 3: 59-62.
- Dorros G., et al., "Clinical Research: Angioplasty," *Circulation Supplement* 1986; 74: 1448; II363.
- Schatz R., et al., "Balloon Expandable Intracoronary Stents in Dogs," *Circulation Supplement* 1986; 74: 1824-II458.
- Radiology 72nd Scientific Assembly and Meeting Agenda*. 1986. Chicago: Nov. 30-Dec. 5.
- American Heart Association 61st Scientific Sessions. Abstract Form. A New Percutaneous Expandable Stent.
- De Palma VA, Baier, Ford JW, Gott VL, Furuse A, "Investigation of Three Surface Properties of Several Metals and their relation to Blood Compatibility," *J Biomed Mater Res Symp* 1972; 3: 37-75.
- Palmaz JC, Tio FO, Schatz RA, Alvarado CR, Garcia O, "Early Endothelialisation of Balloon-expandable Stents: Experimental Observations," *Journal of Interventional Radiology* 1988; 119-124.
- Schatz, Richard, "A View of Vascular Stents," *Circulation* 1989; 79: 445-457.
- Schatz, Richard, "Introduction to Intravascular Stents," *Cardiology Clinics* 1988; vol. 6 No. 3: 357-372.
- Baier RE, Dutton RC, "Initial events in interaction of blood with a foreign surface," *J Biomed Mater Res Symp* 1969; 3: 191-206.
- Palmaz, Julio C., "Balloon-Expandable Intravascular Stent," *AJR*: 150, Jun. 1988: 1263-1269.
- Schatz, Richard A., Palmaz, Julio C., "Intravascular Stents for Angioplasty," *Cardio*, Dec. 1987: 27-31.
- Rosch J., Putnam J., Uchida B., "Gianturco Expandable Stents In Experimental And Clinical Use," Diagnostic Angiography and Interventional, Radiology Course, Mar. 1987; Hand-Out: 121-124.
- Yoshioka, T., Wright K.C., Wallace S., Lawrence D.D. Jr., Ginaturco C., "Self-Expanding Endovascular Graft: An Experimental Study in Dogs," *AJR*, vol. 151 Oct. 1988: 673-676.
- Wright K.C. Ph.D., Wallace S. M.D., Charnsangavej C. M.D., Carrasco, C.H. M.D., Gianturco C. M.D., "Percutaneous Endovascular Stents: An Experimental Evaluation," *Radiology*, 1985; 156: 69-72.
- Rosch et al., "Experimental Intrahepatic Portacaval Anastomosis: Use of Expandable Gianturco Stents," *Radiology*, 1987; 162: 481-485.
- Lawrence, Jr. et al., "Percutaneous Endovascular Graft: Experimental Evaluation," *Radiology*, 1987; 163: 357-360.
- Mirion, M.D. et al., "Percutaneously Placed Endovascular Grafts for Aortic Aneurysms: Feasibility Study," *Radiology*, 1989; 170: 1033-1037.
- Alvarado, R., et al., "Evaluation of Polymer-coated Balloon-expandable Stents in Bile Ducts," 170 *Radiology*, No. 3, Part 2, 975-978 Easton, PA: The Radiological Society of North America (Mar. 1989).
- Becker, G.J., et al., "Simultaneous Angioplasty and Intraluminal Grafting with the Palmaz Expandable Intraluminal Graft," 72nd Scientific Assembly and Annual Meeting of the Radiological Society of North America, Chicago (Nov./Dec. 1986).
- Becker, G.J. et al., "Early Experience with the Palmaz Stent in Human Iliac Angioplasty," *Indiana Medicine*, 286-292 (Apr. 1989).
- Campbell, C.D., et al., "Expanded Microporous Polytetrafluoroethylene as a Vascular Substitute: A Two Year Follow-up," 85 *Surgery*, No. 2, 177-183, St. Louis: C.V. Mosby Co. (Feb. 1979).
- Carrasco, C.H., et al., "Expandable Biliary Endoprosthesis: An Experimental Study," 145 *AJR*, 1279-1281, Baltimore: American Roentgen Ray Society (Dec. 1985).
- Castañeda-Zuñiga, W.R., ed., *Transluminal Angioplasty*, New York: Thieme-Stratton, .iii-207 (1983).
- Charnsangavej, C., et al., "Endovascular Stent for Use in Aortic Dissection: An In Vitro Experiment," 157 *Radiology*, 323-324, Easton, PA: The Radiological Society of North America (1985).
- Cimochowski, G., et al., "Greenfield Filter Versus Mobin-Uddin Umbrella," 79 *Journal of Thoracic and Cardiovascular Surgery*, No. 3, 358-365, St. Louis: C.V. Mosby Co. (Mar. 1980).
- Coons, H., et al., "Large-Bore, Long Biliary Endoprostheses (Biliary Stents) for Improved Drainage," 148 *Radiology*, 89-94, Easton, PA: The Radiological Society of North America (Jul. 1983).
- Cope, C., "Balloon Dilatation of Closed Mesocaval Shunts," 135 *AJR*, 989-993, Baltimore: American Roentgen Ray Society (Nov. 1980).
- Cragg, A., et al., "A New Percutaneous Vena Cava Filter," 141 *AJR*, 601-604, Baltimore: American Roentgen Ray Society (Sep. 1983).
- Cragg, A.H., et al., "Percutaneous Arterial Grafting," 150 *Radiology*, No. 1, 45-49, Easton, PA: The Radiological Society of North America (Jan. 1984).

- Dalessandri, K.M., et al., "The Effect of Lumbar Sympathectomy on Postsynaptic Vascular Smooth Muscle Response in the Lower Limb in Dogs," 11 *Cardiovascular and Interventional Radiology*, 82-85, New York: Springer-Verlag (1988).
- Denny, D., et al., "Percutaneous Kimray-Greenfield Filter Placement by Femoral Vein Puncture," 145 *AJR*, 827-829, Baltimore: American Roentgen Ray Society (Oct. 1985).
- Deriu, G., et al., "The Rationale for Patch-Graft Angioplasty After Carotid Endarterectomy: Early and Long-Term Follow-Up," 15 *Stroke*, No. 6, 972-979, Dallas: American Heart Association (Nov. 1984).
- Dichek, D.A., et al., "Seeding of Intravascular Stents with Genetically Engineered Endothelial Cells," 80 *Circulation* 1347-1353, Dallas: American Heart Association (1989).
- Dorland's Illustrated Medical Dictionary, 26th ed., 1981, pp. 675 & 759, Philadelphia: W.B. Saunders (1981).
- Dotter, C., "Interventional Radiology-Review of an Emerging Field," 16 *Seminars in Roentgenology* No. 1 (Jan. 1981).
- Dotter, C., et al., "Transluminal Treatment of Arteriosclerotic Obstruction," 30 *Circulation*, 654-670, Dallas: American Heart Association (Nov. 1964).
- Edwards, W.S., "Arterial Grafts," 113 *Archives of Surgery*, No. 9, 1225-1233, Chicago: AMA (Nov. 1978).
- Eichelster, P., et al., "Prophylaxis of Pulmonary Embolism," 97 *Archives of Surgery*, 348-356, Chicago: AMA (Aug. 1968).
- Fogarty, T.J., et al., "Adjunctive Intraoperative Arterial Dilation: Simplified Instrumentation Technique," 116 *Archives of Surgery*, 1391-1398, Chicago: AMA (1981).
- Fogarty, T.J., et al., "Current Status of Dilatation Catheters and Guiding Systems," 53 *The American Journal of Cardiology*, No. 12, 97C-100C, New York: Robert T. Brawn (Jun. 1984).
- Fogarty, T.J., et al., "Intraoperative Coronary Artery Balloon-Catheter Dilation," 107 *American Heart Journal*, No. 4, 845-851, St. Louis, C.V. Mosby (1984).
- Gardner, R.J., et al., "The Surgical Experience and a One to Sixteen Year Follow-Up of 277 Abdominal Aortic Aneurysms," 135 *American Journal of Surgery*, No. 1, 226-230 (Jan. 1978).
- Goldstein, H., et al., "Transcatheter Occlusion of Abdominal Tumors," 120 *Radiology*, No. 3, 539-545, Easton, PA: Radiological Society of North America (Sep. 1976).
- Greenfield, L., et al., "A New Intracaval Filter Permitting Continued Flow and Resolution of Emboli," 73 *Surgery*, No. 4, 599-606, St. Louis: C.V. Mosby (Apr. 1973).
- Günther, R. et al., "Vena Caval Filter to Prevent Pulmonary Embolism: Experimental Study," 156 *Radiology*, No. 2, 315-320, Easton, PA: Radiological Society of North America Aug. 1985).
- Harries-Jones, E.P., et al., "Repositioning of Biliary Endoprosthesis with Grüntzig Balloon Catheters," 138 *AJR*, 771-772, Baltimore: American Roentgen Ray Society (Apr. 1982).
- Hoevens, J., et al., "Percutaneous Transhepatic Insertion of a Permanent Endoprosthesis on Obstructive Lesions of the Extrahepatic Bile Ducts," 4 *Gastrointestinal Radiology*, 367-377, New York: Springer-Verlag (1979).
- Honickman, S., et al., "Malpositioned Biliary Endoprosthesis," 144 *Radiology*, 423-425, Easton, PA: Radiological Society of North America (Jul. 1982).
- Hunter, J. et al., "Experimental Balloon Obstruction of the Inferior Vena Cava," 171 *Annals of Surgery*, No. 2, 315-320, J.B. Lippincott (Feb. 1970).
- Inoue, K., et al., "Clinical Application of Transvenous Mitral Commissurotomy by a New Balloon Catheter," 87 *J. Thorac. Cardiovascular Surg.*, No. 3, 394-402, St. Louis: C.V. Mosby (Mar. 1984).
- Kan, J.S., et al., "Percutaneous Balloon Valvuloplasty: A New Method for Treating Congenital Pulmonary-Valve Stenosis," 307 *N. Engl. J. Med.*, No. 9, 540-542, Boston: Massachusetts Medical Society (1982).
- Kerlan, Jr., et al., "Biliary Endoprostheses: Insertion Using a Combined Peroral-Transhepatic Method," 150 *Radiology*, No. 3, 828-830, Easton, PA: Radiological Society of North America (1984).
- Kerlan, R.K., Jr., et al., "A Simple Method for Insertion of Large Untapered Catheters," 141 *AJR*, 792, Baltimore: American Roentgen Ray Society (Oct. 1983).
- Lababidi, Z. et al., "Percutaneous Balloon Aortic Valvuloplasty: Results in 23 Patients," 53 *Am. J. Cardiol*, 194-197, Robert T. Brawn (Jan. 1984).
- Lary, B., et al., "The Experimental Use of Steel Mesh Tubes for the Replacement of Arterial Segments," 72 *AMA Archives of Surgery*, 69-75, Chicago: AMA (Jan. 1956).
- Lewandowski, B., et al., "The Air-Filled Hepatic Duct: The Saber Sign as an Aid to the Radiographic Diagnosis Pneumobilia," 153 *Radiology*, No. 2, 329-332, Easton, PA: Radiological Society of North America (Nov. 1984).
- Lund, G., et al., "A New Vena Caval Filter for Percutaneous Placement and Retrieval: Experimental Study," 152 *Radiology*, No. 2, 369-372, Easton, PA: Radiological Society of North America (Aug. 1984).
- Lunderquist, A., et al., "Guidewire for Percutaneous Transhepatic Cholangiography," 132 *Radiology*, No. 1, 228, Easton, PA: Radiological Society of North America (Jul. 1979).
- Güther, R. M.D., et al., "Percutaneous Nephropylotomy Using a Fine-Needle Puncture Set," 132 *Radiology*, No. 1, 228-230, Easton, PA: Radiological Society of North America (Jul. 1979).
- Mobin-Uddin, K., et al., "Caval Interruption for Prevention of Pulmonary Embolism" 99 *Archives on Surgery*, 711-715, Chicago: AMA (Dec. 1969).
- Mobin-Uddin, K., et al., "The Inferior Vena Cava Umbrella Filter," 17 *Progress in Cardiovascular Diseases*, No. 5, 391-399, Crune & Stratton (Mar./Apr. 1975).
- Nanda, R., et al., "Effect of Maxillary Osteotomy on Subsequent Craniofacial Growth in Adolescent Monkeys," *Am J Orthod* (May 1983).
- Natiella, J.R., et al., "Tissue Response to Surface-Treated Tantalum Implants: Preliminary Observations in Primates," 13 *J. Biomed Mater Res.*, No. 4, 631-643 (Jul. 1979).
- Palestrant, A., et al., "Comparative In Vitro Evaluation of the Nitinol Inferior Vena Cava Filter," 145 *Radiology*, 351-355, Easton, PA: Radiological Society of North America (Nov. 1982).
- Dr. Julio Palmaz's Monograph (1980).
- Palmaz, J., et al., "Removable Biliary Endoprosthesis," 140 *AJR*, 812-814, Baltimore: American Roentgen Ray Society (Apr. 1983).
- Dr. Julio Palmaz's Monography (May 18, 1983).

- Palmaz, J., et al., "Experimental Balloon Expandable Intraluminal Stenting of Normal and Abnormal Renal Arteries," 72nd RSNA Meeting, Chicago, Illinois, pp. 1-23 [plus figures] (Nov. 1986).
- Palmaz, J., et al., "Balloon Expandable Intraluminal Grafting of Normal and Abnormal Renal Arteries: Experimental Study," 72nd Scientific Assembly and Annual Meeting, Radiological Society of North America, Chicago (Nov./Dec. 1986).
- Palmaz, J., et al., "Balloon Expandable Intra-Arterial Stents: Effect of Anticoagulation on Thrombus Formation," 76 *Circulation Supplement*, Part II, No. 4, 0180, Dallas: American Heart Association (Oct. 1987).
- Palmaz, J., et al., "Intraluminal Stents in Atherosclerotic Iliac Artery Stenosis: Preliminary Report of a Multicenter Study," 168 *Radiology*, No. 3, 727-731, Easton, PA: Radiological Society of North America (Sep. 1988).
- Palmaz, J., et al., "Balloon-Expandable Intraarterial Stents: Effect of Antithrombotic Medication on Thrombus Formation," *Pros and Cons in PTA and Auxiliary Methods*, 170-178 (1989).
- Palmaz, J., "Chapter 30: Overview of Intravascular Stents," in Ducksoo Kim and Dan E. Orron, *Peripheral Vascular Imaging and Intervention*, St. Louis: Mosby Year Book, 507-508, (A. Patterson ed. 1992).
- Pate, J., et al., "A New Form of Vena Caval Interruption," 169 *Annals of Surgery*, No. 6, 873-880, J.B. Lippincott (Jun. 1969).
- Puel, J., et al., "Intravascular Stents to Prevent Restenosis After Transluminal Coronary Angioplasty," 76 *Circulation Supplement*, Part II, No. 4, 0105, Dallas: American Heart Association (Oct. 1987).
- Rashkind, W.J., et al., "Creation of an Atrial Septal Defect Without Thoracotomy: A Palliative Approach to Complete Transposition of the Great Arteries," 196 *JAMA*, No. 11, 173-174, Chicago: AMA (Apr.-Jun. 1966).
- Rees, C.R., et al., "The Hemodynamic Effects of the Administration of Ionic and Nonionic Contrast Materials into the Pulmonary Arteries of a Canine Model of Acute Pulmonary Hypertension," 23 *Investigative Radiology*, No. 3, 184-189 (Mar. 1988).
- Rees, C.R., et al., "DSA in Acute Gastrointestinal Hemorrhage: Clinical and in Vitro Studies," 169 *Radiology*, No. 2, 499-503, Easton, PA: Radiological Society of North America (Nov. 1988).
- Rees, C.R., et al., "Angioplasty and Stenting of Completely Occluded Iliac Arteries," 172 *Radiology*, No. 3, Part. 2, 953-959, Easton, PA: Radiological Society of North America (Sep. 1989).
- Richter, G.M., et al., "Der Transjuguläre Intrahepatische Portosystemische Stent-Shunt (TIPSS): Eine Neue Nicht-operative, Perkutane Methode," 29 *Radiologe*, 406-411, Springer-Verlag (1989) [Article includes an English Summary].
- Richter, G.M., et al., "Die Behandlung eines akuten Beckenarterienverschlusses durch Katheterlyse, Katheterdilatation und Implantation einer neuartigen metallischen Gefäßendoprothese," 60 *Der Chirurg*, No. 5, 346-351, Berlin: Springer-Verlag (May 1989) [Article includes an English Summary].
- Ring, E.J., et al., "A Simple, Indwelling Biliary Endoprosthesis Made From Common Available Catheter Material," 139 *AJR*, 615-617, Baltimore: American Roentgen Ray Society (Sep. 1982).
- Roehm, Jr., et al., "Percutaneous Transcatheter Filter for the Inferior Vena Cava," 150 *Radiology*, No. 1, 255-257, Easton, PA: Radiological Society of North America (Jan. 1984).
- Rollins, N., et al., "Self-Expanding Metallic Stents: Preliminary Evaluation in an Atherosclerotic Model," 163 *Radiology*, No. 3, 739-742, Easton, PA: Radiological Society of North America (Jun. 1987).
- Rosch, J., et al., "Transjugular-Intrahepatic Portacaval Shunt: An Experimental Work," 121 *The American Journal of Surgery*, 588-592, New York: Reuben H. Donnelley (May 1971).
- Rousseau, H., et al., "Percutaneous Vascular Stent: Experimental Studies and Preliminary Clinical Results in peripheral Arterial Diseases," *Inter. Angio.* 6, 153-161 (1987).
- Schatz, R., et al., "Balloon Expandable Intravascular Grafts," 16th Annual Symposium of the Texas Health Institute-International Symposium on Interventional Cardiology, Houston (Sep. 1986).
- Schatz, R., et al., "Balloon Expandable Intracoronary Stents in the Adult Dog," 59th Scientific Sessions of the American Heart Association Meeting, Dallas (Nov. 1986).
- Schatz, R., et al., "Balloon Expandable Intracoronary Stents in the Adult Dog," 76 *Circulation* No. 2, 450-457, Dallas: American Heart Association (Aug. 1987).
- Schatz, R., et al., "New Technology in Angioplasty: Balloon-Expandable Intravascular Stents," 2 *New Developments in Medicine*, No. 2, 59-75 (Sep. 1987).
- Semb, B.K.H., et al., "Balloon Valvulotomy of Congenital Pulmonary Valve Stenosis with Tricuspid Valve Insufficiency," 2 *Cardiovascular Radiology*, 239-241, New York: Springer-Verlag (1979).
- Sigwart, U., et al., "One Year of Percutaneous Coronary Stenting," 76 *Circulation Supplement*, Part II, No. 4, 0104, Dallas: American Heart Association (Oct. 1987).
- Sigwart, U., et al., "Initial Experience With A New Approach to Stenting of Peripheral and Coronary Arteries," (date unknown).
- Simon, M., et al., "A Vena Cava Filter Using Thermal Shape Memory Alloy," 125 *Radiology*, 89-94, Easton, PA: Radiological Society of North America (Oct. 1977).
- Smith, D., et al., "Safe and Effective Catheter Angiography Through Prosthetic Vascular Grafts," 138 *Radiology*, No. 2, 487-488, Easton, PA: Radiological Society of North America (Feb. 1981).
- Solberg, S., et al., "Cold Induced Endothelial Cell Detachment in Human Saphenous Vein Grafts," 28 *Journal of Cardiovascular Surgery*, No. 5, 571-575, Minerva Medica (Sep.-Oct. 1987).
- Stack, R., M.D., "A New Highly Flexible Balloon-Expandable Endovascular Stent: Initial Experimental Results and Up To Six Months Follow-up," Laser One Meeting, Newport Beach, California (May 11-13, 1989).
- Strecker, E.P., et al., "Perkutan Implantierbare, Durth Balloon Aufdehnbare Gefäßprothese," 113 *Disch Med Wschr*, No. 14, 538-542, Stuttgart: Georg Thieme Verlag (1988) [Article includes an English Summary].
- Teplick, S.K., et al., "A New Biliary Endoprosthesis," 141 *AJR*, 799-801, Baltimore: American Roentgen Ray Society (Oct. 1983).
- Trent, M., M.D., et al., "An Expandable Intravascular Stent for the Maintenance of Luminal Patency," Division of Vascular Surgery and the Department of Surgery, Newark Beth Israel Medical Center, date unknown.

Journal of the American College of Cardiology 2(Supplement A): 106A, (from Abstracts of the 36th Annual Scientific Session, American College of Cardiology, New Orleans, Louisiana Mar. 8-12, 1987), Elsevier (Feb. 1987).

Plaintiff Advanced Cardiovascular System's Answering Brief in Opposition to Defendant's Motion to Disqualify Lead Trial Counsel, Advanced Cardiovascular Systems, Inc. v. Arterial Vascular Engineering, Inc., C.A. No. 98-314-SLR (D. Del. Brief dated Sep. 18, 1998) (includes Exhibits A-W).

Answer and Counterclaim of Advanced Cardiovascular Systems, Inc. and Guidant Sales Corporation to Amended and Supplemental Complaint of Medtronic AVE, Inc. and Medtronic USA, Inc., Medtronic AVE, Inc. et al. v. Advanced Cardiovascular Systems, Inc., et al., C.A. No. 98-80-SLR (D. Del., Answer and Counterclaim dated Nov. 9, 2000).

Answer to Second Amended Complaint, Affirmative Defenses and Counterclaims, Medtronic AVE, Inc. et al. v. Boston Scientific Corp., et al., C.A. No. 98-478-SRL (D. Del. Answer dated Jul. 13, 2000).

First Amended Complaint Asserting Derivative and Individual Causes of Action for Breach of Contract; Breach of Covenant of Good Faith and Fair Dealing; Breach of Fiduciary Duty; Misappropriation of Trade Secrets; Unfair Competition; Intentional Misrepresentation; Concealment; Non-disclosure; Unjust Enrichment and Breach of Confidence, Rodolfo Di Massa, M.D., et al., v. Simon Stertz, M.D., et

al., No. 222363 (Cal. Super. Ct., Sonoma County, First Amended Complaint filed Feb. 1, 2000) (Includes Exhibit A).

Rodolfo Di Massa's Supplemental Answers to Defendant Medtronic Arterial Vascular Engineering Inc.'s First Set of Specially Prepared Interrogatories, Rodolfo Di Massa, M.D., et al., v. Simon Stertz, M.D., et al., No. 222363 (Cal. Super. Ct., Sonoma County, Supplemental Answers dated Mar. 15, 2000).

Declaration of Paul Bonneau, Jr., Rodolfo Di Massa, M.D., et al. v. Simon Stertz, M.D., et al., No. 222363 (Cal. Super Ct., Sonoma County, Declaration dated May 12, 2000) (including Exhibits D1-D3).

Plaintiff's Eight Amended Petition, Azam Anwar, M.D., et al. v. Arterial Vascular Engineering, Inc., No. 96-05323-M (Tex. Dist. Ct., Dallas County, 298th Judicial Dist., Petition dated Oct. 28, 1998).

Urteil [Judgment], Inflow Dynamics AG, et al. v. Arterial Vascular Engineering, Inc., Nos. 4 Ni 33/99 (EU) verb. [joined with] 4 Ni 41/99 (EU) (Bundespatentgericht [BPatG] [Federal Court for Patent Matters] Sep. 5, 2000) [English Translation included].

* cited by examiner

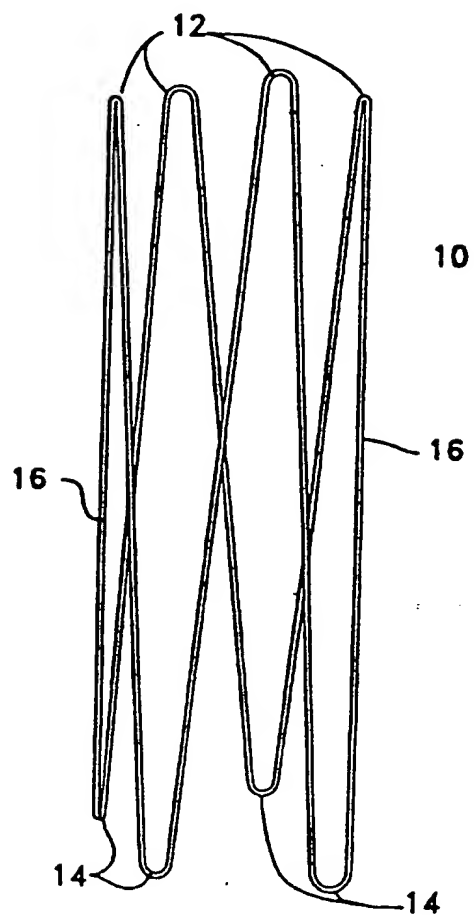


Figure 1

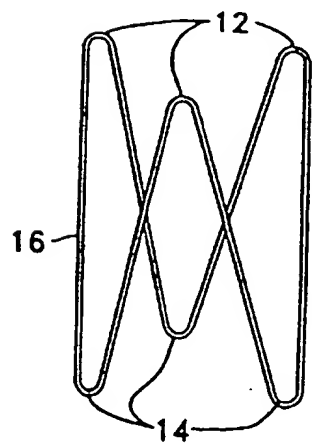


Figure 6a

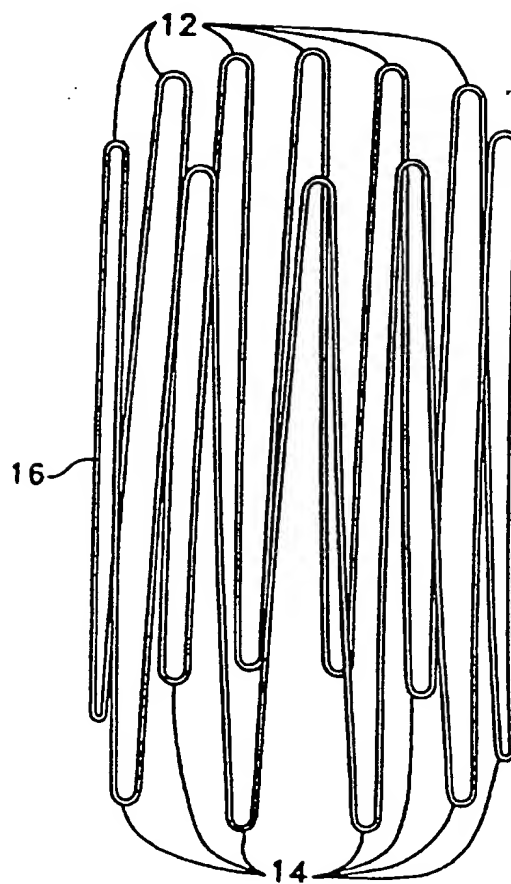


Figure 6b

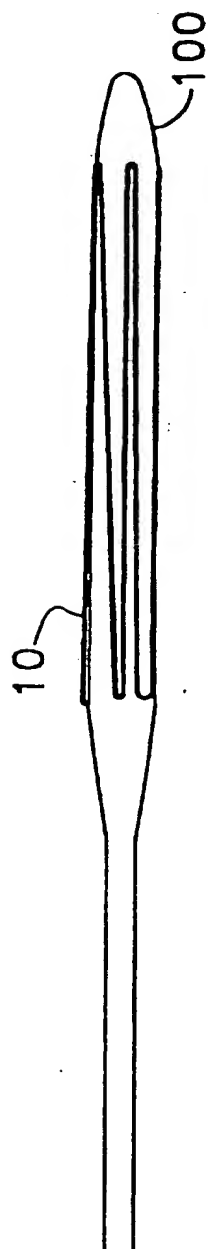


Figure 2

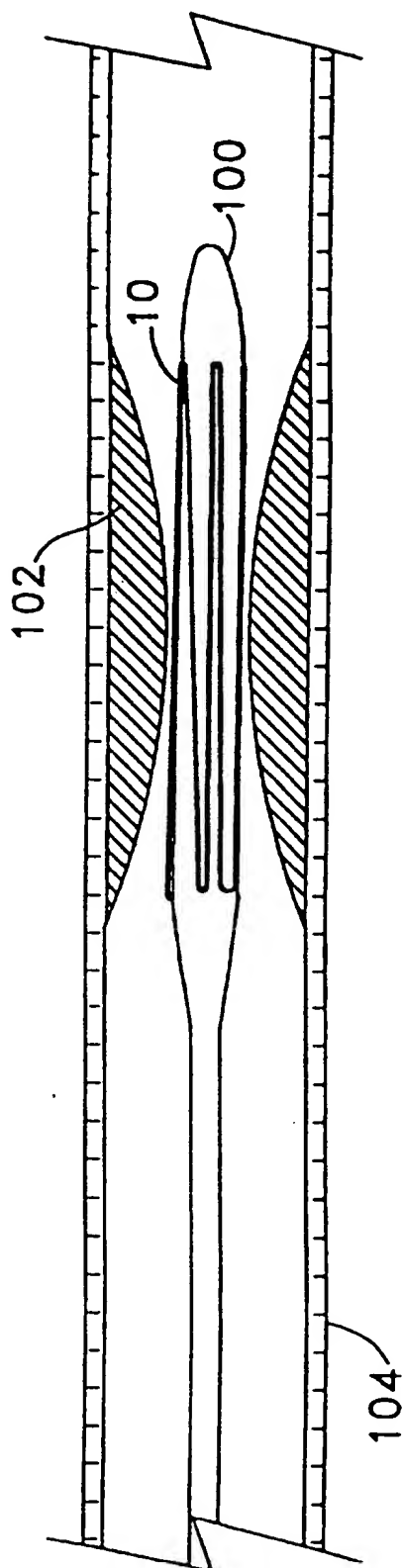


Figure 3

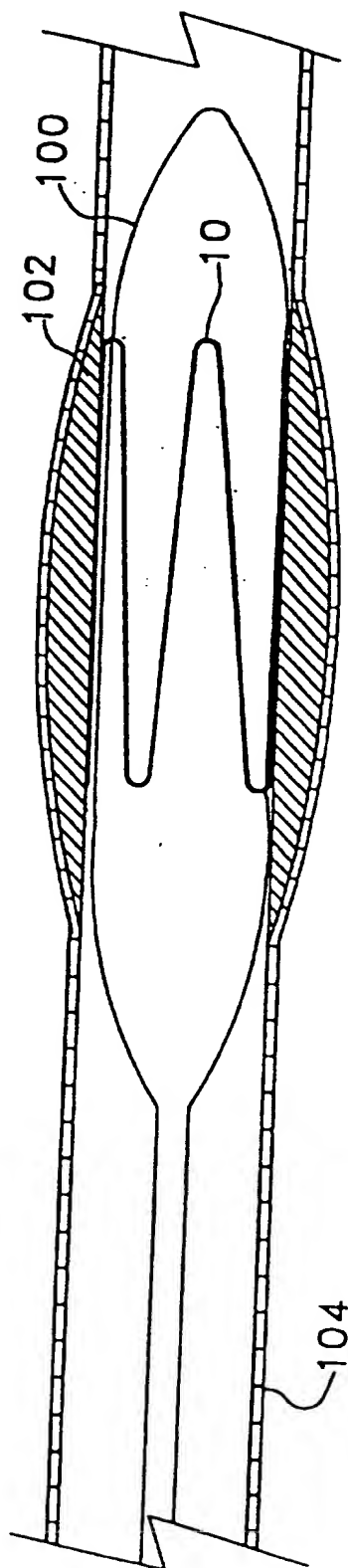


Figure 4

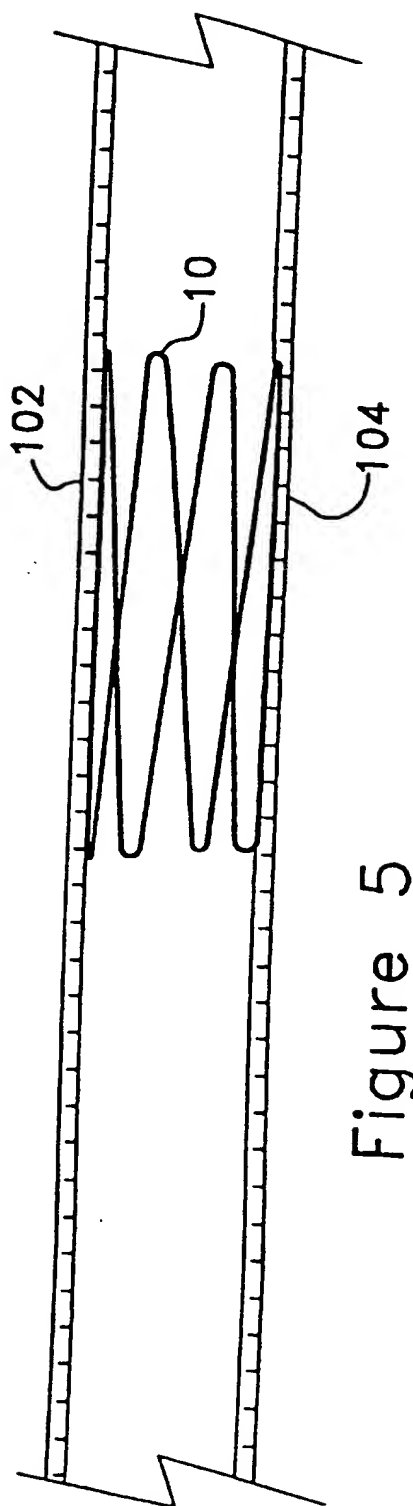


Figure 5

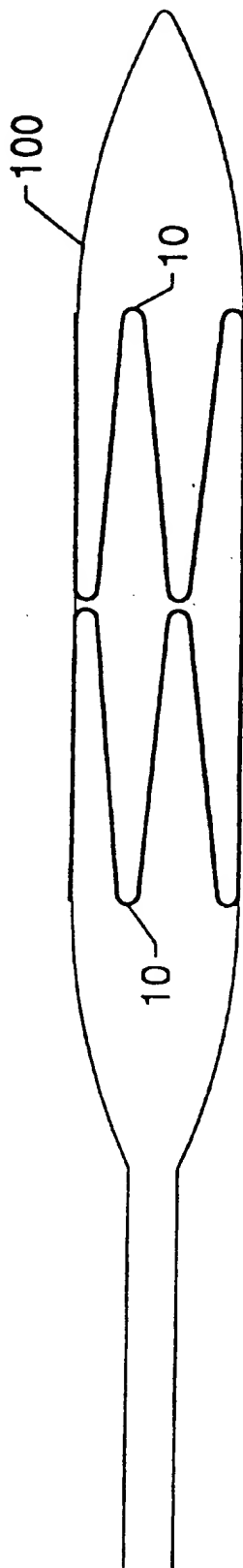


Figure 7

ENDOVASCULAR SUPPORT DEVICE AND METHOD

This application is a continuation of application Ser. No. 08/471,738, filed Jun. 6, 1995, now U.S. Pat. No. 5,891,140, which is a divisional of Ser. No. 08/172,420, filed on Dec. 22, 1993, now abandoned, which is a division of application Ser. No. 07/398,180, filed Aug. 24, 1989, now U.S. Pat. No. 5,292,331.

FIELD OF THE INVENTION

The present invention relates generally to medical devices and particularly relates to implantable devices for treating narrowing of coronary or peripheral vessels in humans.

BACKGROUND OF THE INVENTION

Cardiovascular disease, including atherosclerosis, is the leading cause of death in the U.S. The medical community has developed a number of methods for treating coronary heart disease, some of which are specifically designed to treat the complications resulting from atherosclerosis and other forms of coronary arterial narrowing.

The most impelling development in the past decade for treating atherosclerosis and other forms of coronary narrowing is percutaneous transluminal coronary angioplasty, hereinafter referred to simply as "angioplasty" or "PTCA". The objective in angioplasty is to enlarge the lumen of the affected coronary artery by radial hydraulic expansion. The procedure is accomplished by inflating a balloon within the narrowed lumen of the coronary artery. Radial expansion of the coronary artery occurs in several different dimensions and is related to the nature of the plaque. Soft, fatty plaque deposits are flattened by the balloon and hardened deposits are cracked and split to enlarge the lumen. The wall of the artery itself is also stretched when the balloon is inflated.

PTCA is performed as follows: A thin-walled, hollow guiding catheter is typically introduced into the body via a relatively large vessel, such as the femoral artery in the groin area or the brachial artery in the arm. Access to the femoral artery is achieved by introducing a large bore needle directly into the femoral artery, a procedure known as the Seldinger Technique. Once access to the femoral artery is achieved, a short hollow sheath is inserted to maintain a passageway during PTCA. The flexible guiding catheter, which is typically polymer coated, and lined with Teflon, is inserted through the sheath into the femoral artery. The guiding catheter is advanced through the femoral artery into the iliac artery and into the ascending aorta. Further advancement of the flexible catheter involves the negotiation of an approximately 180 degree turn through the aortic arch to allow the guiding catheter to descend into the aortic cusp where entry may be gained to either the left or the right coronary artery, as desired.

After the guiding catheter is advanced to the ostium of the coronary artery to be treated by PTCA, a flexible guidewire is inserted into the guiding catheter through a balloon and advanced to the area to be treated. The guidewire provides the necessary steerability for lesion passage. The guidewire is advanced across the lesion, or "wires" the lesion, in preparation for the advancement of a polyethylene, polyvinyl chloride, polyolefin, or other suitable substance balloon catheter across the guide wire. The balloon, or dilatation, catheter is placed into position by sliding it along the guide wire. The use of the relatively rigid guide wire is necessary to advance the catheter through the narrowed lumen of the artery and to direct the balloon, which is typically quite

flexible, across the lesion. Radiopaque markers in the balloon segment of the catheter facilitate positioning across the lesion. The balloon catheter is then inflated with contrast material to permit fluoroscopic viewing

during treatment. The balloon is alternately inflated and deflated until the lumen or the artery is satisfactorily enlarged.

Unfortunately, while the affected artery can be enlarged, in some instances the vessel restenoses chronically, or closes down acutely, negating the positive effects of the angioplasty procedure. In the past, such restenosis has frequently necessitated repeat PTCA or open heart surgery. While such restenosis does not occur in the majority of cases, it occurs frequently enough that such complications comprise a significant percentage of the overall failures of the PTCA procedure, for example, twenty-five to thirty-five percent of such failures.

To lessen the risk of restenosis, various devices have been proposed for mechanically keeping the affected vessel open after completion of the angioplasty procedure. Such mechanical endoprosthetic devices, which are generally referred to as stents, are typically inserted into the vessel, positioned across the lesion, and then expanded to keep the passageway clear. Effectively, the stent overcomes the natural tendency of the vessel walls of some patients to close back down, thereby maintaining a more normal flow of blood through that vessel than would be possible if the stent were not in place.

Various types of stents have been proposed, although to date none has proven satisfactory. One proposed stent involves a tube of stainless wire braid. During insertion, the tube is positioned along a delivery device, such as a catheter, in extended form, making the tube diameter as small as possible. When the stent is positioned across the lesion, it is expanded, causing the length of the tube to contract and the diameter to expand. Depending on the materials used in construction of the stent, the tube maintains the new shape either through mechanical force or otherwise. For example, one such stent is a self-expanding stainless steel wire braid. Other forms of stents include various types tubular metallic cylinders expanded by balloon dilatation. One such device is referred to as the Palmaz stent, discussed further below.

Another form of stent is a heat expandable device. This device, originally designed using NITINOL by Dotter has recently been modified to a new tin-coated, heat expandable coil by Regan. The stent is delivered to the affected area on a catheter capable of receiving heated fluids. Once properly positioned, heated saline is passed through the portion of the catheter on which the stent is located, causing the stent to expand. Numerous difficulties have been encountered with this device, including difficulty in obtaining reliable expansion, and difficulties in maintaining the stent in its expanded state.

Perhaps the most popular stent presently under investigation in the United States is referred to as the Palmaz stent. The Palmaz stent involves what may be thought of as a stainless steel cylinder having a number of slits in its circumference, resulting in a mesh when expanded. The stainless steel cylinder is delivered to the affected area by means of a balloon catheter, and is then expanded to the proper size by inflating the balloon.

Significant difficulties have been encountered with all prior art stents. Each has its percentage of thrombosis, restenosis and tissue in-growth, as well as varying degrees of difficulty in deployment. Another difficulty with at least some of prior art stents is that they do not readily conform

3

to the vessel shape. In addition, the relatively long length of such prior art stents has made it difficult to treat cursed vessels, and has also effectively prevented successful implantation of multiple such stents. Anticoagulants have historically been required at least for the first three months after placement. These and other complications have resulted in a low level of acceptance for such stents within the medical community, and to date stents have not been accepted as a practical method for treating chronic restenosis.

Thus there has been a long felt need for a stent which is effective to maintain a vessel open, without resulting in significant thrombosis, which may be easily delivered to the affected area, easily expanded to the desired size, easily conformed to the affected vessel, and easily used in multiples to treat curved vessels and varying lengths of lesions.

SUMMARY OF THE INVENTION

The present invention substantially reduces the complications and overcomes the limitations of the prior art devices. The endovascular support device of the present invention comprises a device having very low mass which is capable of being delivered to the affected area by means of a slightly modified conventional balloon catheter similar to that used in a standard balloon angioplasty procedure.

The support device of the present invention may then be expanded by normal expansion of the balloon catheter used to deliver the stent to the affected area, and its size can be adjusted within a relatively broad range in accordance with the diagnosis of the treating physician.

Because of the range of diameters through which the support device of the present invention may be expanded, it may be custom expanded to the specific lesion diameter, and is readily conformable to the vessel shape. In addition, a plurality of support devices of the present invention may be readily implanted in a number commensurate with the length of the lesion under treatment. As a result, curved or "S" shaped vessels may be treated.

The stent, or endovascular support device, of the present invention may preferably be comprised of implantable quality high grade stainless steel, machined specially for intravascular applications. The support device may comprise, in effect, a metal circle or ellipsoid formed to create a plurality of axial bends, thereby permitting compression of the stent onto a delivery catheter, and subsequent expansion once in place at the affected area.

It is one object of the present invention to provide a stent which substantially overcomes the limitations of the prior art.

It is a further object of the present invention to provide a stent capable of being implanted simply and reliably.

Another object of the present invention is to provide a stent which does not result in significant thrombosis at the point of implant.

Yet another object of the present invention is to provide a stent which can be selectively sized in accordance with the anatomic configuration dictated by the lesion itself.

A still further object of the present invention is to provide a method for supplying an endovascular support device which permits a plurality of such devices to be implanted commensurate with the length of the lesion under treatment.

These and other objects of the present invention can be better appreciated from the following detailed description of the invention, taken in conjunction with the attached drawings.

FIGURES

FIG. 1 shows a perspective view of an endovascular support device constructed according to the present invention, in its expanded form.

4

FIG. 2 shows a support device constructed according to the present invention and compressed onto a balloon catheter.

FIG. 3 shows a support device compressed onto a balloon catheter as shown in FIG. 2 and positioned within a sectioned portion of an affected area of an artery or other vessel.

FIG. 4 shows a support device according to the present invention in its expanded form within a sectioned portion of a vessel including a lesion.

FIG. 5 shows a support device of the present invention in its expanded form within a sectioned portion of a lesion after removal of the balloon catheter.

FIGS. 6a-b show alternative configurations of a support device according to the present invention.

FIG. 7 shows an alternate configuration of a support device constructed according to the present invention and compressed into a balloon catheter.

DETAILED DESCRIPTION OF THE INVENTION

Referring first to FIG. 1, an endovascular support device 10, referred to hereinafter more conveniently as a stent, constructed in accordance with the present invention can be seen in perspective view. The stent 10 of FIG. 1 is shown in its expanded form, prior to compression over a suitable delivery system as discussed in detail hereinafter.

In a preferred embodiment, the stent 10 comprises a single piece of material, bent to form a plurality of upper axial turns 12 and lower axial turns 14. In the embodiment shown in FIG. 1, four upper turns 12 are connected to the four lower turns 14 by substantially straight segments 16. The axial turns 12 and 14 can be seen to permit the stent 10 to be compressed or expanded over a wide range while still maintaining significant mechanical force, such as required to prevent a vessel from restenosing. While a preferred embodiment comprises a single piece of material, in some instances a suitably welded wire may be acceptable.

It will be appreciated that the number of turns 12 and 14 can vary over a reasonably wide range and may in fact vary between two and ten such turns or peaks. However, it is currently believed that the optimum number of turns or peaks will range between three and five for most applications, and particularly for cardiovascular applications.

The stent 10 is preferably constructed of implantable materials having good mechanical strength. An embodiment which has proven successful in preliminary testing is machined from 316LSS implantable quality stainless steel bar stock. The bar stock is machined to form substantially a toroid, which is then acid etched in phosphoric and sulfuric acid at approximately 180° to 185° to break the edges. The etched toroid is then plated with copper to avoid galling and to provide lubricity.

The copper plated toroid is then bent to the shape of the stent 10 shown in FIG. 1, after which the copper plating is stripped from the stent. The stent is then returned to the acid bath to reduce the wire size to the desired diameter, which is in the range of 0.002" to 0.025". It is presently believed that the optimum wire size for the final product is in the range of 0.008" to 0.009". It will be appreciated that the strength of the stent—that is, its ability to prevent restenosis—is inversely proportional to the number of peaks or turns in the stent, so that stents having a greater number of turns will typically be formed of larger wire diameters. Finally, although not required in all cases, the outside of the stent may be selectively plated with platinum to provide improved visibility during fluoroscopy. The cross-sectional shape of the finished stent may be circular, ellipsoidal,

5

rectangular, hexagonal, square, or other polygon, although at present it is believed that circular or ellipsoidal may be preferable.

The minimum length of the stent, or the distance between the upper turns 12 and lower turns 14, is determined in large measure by the size of the vessel into which the stent will be implanted. The stent 10 will preferably be of sufficient length as to maintain its axial orientation within the vessel without shifting under the hydraulics of blood flow (or other fluid flow in different types of vessels), while also being long enough to extend across at least a significant portion of the affected area. At the same time, the stent should be short enough as to not introduce unnecessarily large amounts of material as might cause undue thrombosis. Typical cardiovascular vessels into which the stent 10 might be implanted range from 1.5 millimeters to five millimeters in diameter, and corresponding stents may range from one millimeter to two centimeters in length. However, in most instances the stent will range in length between 3.5 millimeters and 6 millimeters. Preliminary testing of stents having a length between 3.5 millimeters and 4.5 millimeters has been performed with good success outside the United States, and testing on animals is also ongoing.

Once the wire size of the stent 10 has been reduced to the desired size, the stent 10 may be crimped onto a balloon 100, as shown in FIG. 2, for delivery to the affected region 102 of a vessel 104 such as a coronary artery. For the sake of simplicity, the multiple layers of the vessel wall 104 are shown as a single layer, although it will be understood by those skilled in the art that the lesion typically is a plaque deposit within the intima of the vessel 104.

One suitable balloon for delivery of the stent 10 is manufactured by Advanced Cardiovascular Systems, Inc., of Santa Clara, Calif. ("ACS"), and is eight millimeters in length with Microglide on the shaft only. The stent-carrying balloon 100 is then advanced to the affected area and across the lesion 102 in a conventional manner, such as by use of a guide wire and a guide catheter (not shown). A suitable guide wire is the 0.014" Hi Torque Floppy manufactured by ACS, and a suitable guiding catheter is the ET0.076 lumen guide catheter, also manufactured by ACS.

Once the balloon 100 is in place across the lesion 102, as shown in FIG. 3, the balloon 100 may be inflated, again substantially in a conventional manner. In selecting a balloon, it is helpful to ensure that the balloon will provide radially uniform inflation so that the stent 10 will expand equally along each of the peaks. The inflation of the balloon 100, shown in FIG. 4, causes the expansion of the stent 10 from its crimped configuration back to a shape substantially like that shown in FIG. 1. The amount of inflation, and commensurate amount of expansion of the stent 10, may be varied as dictated by the lesion itself, making the stent of the present invention particularly flexible in the treatment of chronic restenosis.

Because of the inflation of the balloon, the lesion 102 in the vessel 104 is expanded, and causes the arterial wall of the vessel 104 to bulge radially, as simplistically depicted in FIG. 4. At the same time, the plaque deposited within the intima of the vessel is displaced and thinned, and the stent 10 is embedded in the plaque or other fibrotic material adhering to the intima of the vessel 104.

Following inflation of the balloon 100 and expansion of the stent 10 within the vessel 104, the balloon is deflated and removed. The exterior wall of the vessel 104 returns to its original shape through elastic recoil. The stent 10, however, remains in its expanded form within the vessel, and prevents further restenosis of the vessel. The stent maintains an open passageway through the vessel, as shown in FIG. 4, so long as the tendency toward restenosis is not greater than the mechanical strength of the stent 10. Because of the low mass

6

of the support device 10 of the present invention, thrombosis is less likely to occur. Ideally, the displacement of the plaque deposits and the implantation of the stent 10 will result in a smooth inside diameter of the vessel 104, although this ideal cannot be achieved in all cases.

One of the advantages of the stent 10 is that multiple stents may be used in the treatment of a single lesion. Thus, for example, in the event the affected area shown in FIGS. 3 and 4 was longer than the stent 10, additional stents 10 could be positioned elsewhere along the lesion to prevent restenosis. In preliminary testing, up to four stents have been used successfully along a single lesion. Due to the conformability of the stent 10, not only can varying lesion lengths be treated, but curved vessels and "S" shaped vessels may also be treated by the present invention. In instances where it is known in advance that multiple stents will be the preferred method of treatment, a plurality of such stents may be positioned along a single balloon catheter for simultaneous delivery to the affected area as shown in FIG. 7.

As discussed above, the number of peaks or turns 12 and 14 in the stent 10 may vary between two and ten. To this end, shown in FIGS. 6a and 6b are two alternative configurations of the stent 10. The alternative embodiment shown in 6a can be seen to have three upper and three lower peaks or turns, while the embodiment shown in FIG. 6b can be seen to have ten upper and ten lower peaks.

While the primary application for the stent 10 is presently believed to be treatment of cardiovascular disease such as atherosclerosis or other forms of coronary narrowing, the stent 10 of the present invention may also be used for treatment of narrowed vessels in the kidney, leg, carotid, or elsewhere in the body in such other vessels the size of the stent may need to be adjusted to compensate for the differing sizes of the vessel to be treated, bearing in mind the sizing guidelines provided above.

Having fully described a preferred embodiment of the invention, those skilled in the art will immediately appreciate, given the teachings herein, that numerous alternatives and equivalents exist which do not depart from the present invention. It is therefore to be understood that the present invention is not to be limited by the foregoing description, but only by the appended claims.

I claim:

1. A balloon-expandable stent comprising:

a plurality of generally sinusoidally-shaped, plastically deformable rings capable of retaining a compressed configuration when mounted onto a balloon catheter and having a first diameter when mounted onto the balloon catheter;

each ring comprising substantially straight segments oriented generally parallel to a longitudinal axis of its ring in its first diameter;

each segment having a first end and a second end, with a first end of a first segment connected to a first end of a second segment by a first turn;

a second end of the second segment connected to a second end of a third segment by a second turn;

a first end of the third segment connected to a first end of a fourth segment by a third turn, and so on until a second end of an Nth segment is connected to a second end of the first segment by an Nth turn;

wherein each segment is connected to another segment at its ends and at no point intermediate its ends; and

wherein the rings are expandable to a second diameter larger than the first diameter.

2. The stent of claim 1, wherein the segments have a generally hexagonal cross-section.

7

3. The stent of claim 1, wherein the segments have a generally rectangular cross-section.

4. The stent of claim 1, wherein the segments have a generally round cross-section.

5. The stent of claim 1, wherein the rings are not connected to each other.

6. The stent of claim 1, wherein the rings are formed from a toroid.

7. The stent of claim 1, wherein the turns are curved.

8. A balloon-expandable stent for implantation within a vessel within the human body comprising:

a plurality of plastically deformable generally sinusoidally-shaped circular members; each circular member including a plurality of substantially straight segments, each segment having a first and second ends, wherein the first end of a first segment is connected to the first end of a second segment; the second end of the second segment is connected to the second end of the third segment; the first end of the third segment is connected to the first end of the fourth segment, and so on until the second end of a last segment is connected to the second end of the first segment, each circular member capable of retaining a compressed configuration while mounted onto an outer surface of a balloon catheter until application of a radial force to form an expanded configuration.

9. The stent of claim 8, wherein the segments have a generally hexagonal cross-section.

10. The stent of claim 8, wherein the segments have a generally rectangular cross-section.

11. The stent of claim 8, wherein the segments have a generally round cross-section.

12. The stent of claim 8, wherein the generally sinusoidally-shaped circular members are not connected to each other.

13. The stent of claim 8, wherein the generally sinusoidally-shaped circular members are formed from a toroid.

14. The stent of claim 8, wherein all segments are aligned in a generally same direction, when in a compressed configuration mounted on an outer surface of a balloon catheter.

15. The stent of claim 8, wherein all segments are aligned generally parallel to a longitudinal axis of the stent, when in a compressed configuration mounted on an outer surface of a balloon catheter.

16. A balloon-expandable stent comprising:

a plurality of adjacent and non-overlapping, generally circular members, each circular member including a plurality of substantially straight, non-overlapping segments having ends;

the ends of respective pairs of the plurality of segments connected to each other, the segments not connected at any point intermediate their ends;

each circular member capable of retaining a compressed configuration while mounted onto an outer surface of a balloon catheter until application of a radial force to form an expanded configuration; and

wherein each segment is aligned generally parallel to a longitudinal axis of the balloon catheter, when in a compressed configuration mounted on an outer surface of a balloon catheter.

17. The stent of claim 16, wherein the segments have a generally hexagonal cross-section.

18. The stent of claim 16, wherein the segments have a generally rectangular cross-section.

8

19. The stent of claim 16, wherein the segments have a generally round cross-section.

20. The stent of claim 16, wherein the generally circular members are not connected to each other.

21. The stent of claim 16, wherein the generally circular members are formed from a toroid.

22. The stent of claim 16, wherein all segments are aligned in a generally same direction, when in a compressed configuration mounted on an outer surface of a balloon catheter.

23. The stent of claim 16, wherein all segments are aligned generally parallel to a longitudinal axis of the stent, when in a compressed configuration mounted on an outer surface of a balloon catheter.

24. A stent delivery system comprising:

a delivery catheter having a balloon portion and a longitudinal axis;

a balloon-expandable stent mounted on the balloon portion and including a plurality of plastically deformable substantially straight segments having opposed ends, and arranged circumferentially around the balloon catheter; and

each segment being connected to adjacent segments at its ends by curved members, each segment not connected to the adjacent segments at any point intermediate its ends, each curved member having substantially the same cross-section as the segments, wherein the balloon-expandable stent is capable of retaining a compressed configuration while mounted on the balloon catheter with each segment being oriented substantially parallel to the longitudinal axis when in the compressed configuration.

25. The stent delivery system of claim 24, wherein the segments have a substantially rectangular cross-section.

26. The stent delivery system of claim 24, wherein the curved members connect circumferentially adjacent segments.

27. A stent delivery system comprising:

a delivery catheter having an inflatable balloon and a longitudinal axis;

a plurality of plastically deformable balloon-expandable endovascular support members, mounted on the inflatable balloon and capable of retaining a compressed configuration when mounted on the balloon until application of a radial force by inflation of the balloon; each plastically deformable balloon-expandable endovascular support member including a plurality of substantially straight segments having opposed ends, and arranged circumferentially around the inflatable balloon; and each substantially straight segment, of each plastically deformable balloon-expandable endovascular support member, being connected to circumferentially adjacent segments at its ends and not at any point intermediate of its ends; and wherein the plurality of endovascular support members are positioned along the inflatable balloon for simultaneous deployment.

28. The stent of claim 27, wherein the segments have a generally rectangular cross-section.

29. The stent of claim 27, wherein the segments have a generally round cross-section.

30. The stent as defined in claim 27, wherein the connections of opposed ends defines a series of upper and lower turns alternating in a circumferential direction.

* * * * *

**United States
Patent and
Trademark Office**

Return To:

USPTO
Home
PageFinance
Home
Page

Patent Number: 6344053

Application Number: 09287216

Entity Status: Large	Filing Date:	04/05/1999	Window Open:	02/07/2005
	Issue Year:	02/05/2002	Surcharge Due:	08/08/2005
	Payment Year:		Window Close:	02/06/2006

Need Help?

Customer Number:	000000
Customer Address:	IP LEGAL Medtronic Ave, Inc
City:	Santa Rosa
State:	CA
Zip:	95403
Phone:	(000) 000-0000

No Fees to Pay

If you prefer NOT to pay by Credit Card over the Internet, you may download the form and mail to:
United States Patent and Trademark Office
P.O. Box 371611
Pittsburgh, PA 15250-1611

[Download Form](#)

Please note that in order to you view the form you must have Adobe's Acrobat Reader installed. If you do not have it, download it FREE!

[Need Help?](#) | [Return to USPTO Home Page](#) | [Return to Office of Finance Home P:](#)

9

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 6,344,053 B1
DATED : February 5, 2002
INVENTOR(S) : Michael D. Boneau

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:


Title page.

Related U.S. Application Data, delete "which is a division of application No. 07/398,180, filed on August 24, 1999, now Pat. No. 5,292,331." and substitute -- which is a division of application No. 07/398,180, file on August 24, 1989, now Pat. No. 5,292,331. -- therefor.

Signed and Sealed this

Twenty-second Day of October, 2002

Attest:



Attesting Officer

JAMES E. ROGAN
Director of the United States Patent and Trademark Office

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

☐ BLACK BORDERS

☒ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES

☐ FADED TEXT OR DRAWING

☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING

☐ SKEWED/SLANTED IMAGES

☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS

☐ GRAY SCALE DOCUMENTS

☐ LINES OR MARKS ON ORIGINAL DOCUMENT

☒ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY

☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.